

EPA REGISTRATION NUMBER 71693-1 – VOLUME 4

FedEx USA Airbill
Express

Tracking Number 837714994584

1 From *Please print or type name*
Date 6/27/03 Sender's FedEx Account Number
Sender's Name S. Bacchus Phone (703) 308-8097
Co. EPA CM-2 #910
Address 1921 Jefferson Davis HWY
City ARLINGTON State VA ZIP 22202

2 Your Internal Billing Reference
3 To Recipient's Name Larry Antilla Phone (602) 438-0407
Company Arizona Cotton Research
Address 3721 East Wier Avenue, AZ
City Phoenix State AZ ZIP 85040

State ZIP

Try online shipping at fedex.com

By using this Airbill you agree to the service conditions on the back of this Airbill and in our current Service Guide, including terms that limit our liability.

Questions? Visit our Web site at fedex.com or call 1.800.Go.FedEx® 800.463.3339.

0200

Sender's Copy

4a Express Package Service
☐ FedEx Priority Overnight
☒ FedEx Standard Overnight
☐ FedEx 2Day
☐ FedEx 3Day Freight

4b Express Freight Service
☐ FedEx 1Day Freight
☐ FedEx 2Day Freight
☐ FedEx 3Day Freight

5 Packaging
☒ FedEx Envelope
☐ FedEx Pak
☐ Other

6 Special Handling
☐ SATURDAY Delivery
☐ HOLD Weekday
☐ HOLD Saturday
☐ at FedEx Location

7 Payment Bill to:
☐ Sender
☒ Recipient
☐ Third Party
☐ Credit Card
☐ Cash/Check

Total Packages Total Weight Total Declared Value
FedEx Act No. 1144 34 000

8 Release Signature
Your liability is limited to \$100 unless you declare a higher value. See back for details.
Signature: *[Signature]*

By signing this Airbill you agree to the service conditions on the back of this Airbill and in our current Service Guide, including terms that limit our liability.

Questions? Visit our Web site at fedex.com or call 1.800.Go.FedEx® 800.463.3339.

446

Terms And Conditions

Definitions On this Airbill, "we," "our," and "us" refer to Federal Express Corporation, its employees, and agents. "You" and "your" refer to the sender, its employees, and agents.

Agreement To Terms By giving us your package to deliver, you agree to all the terms on this Airbill and in our current Service Guide, which is available on request. You also agree to those terms on behalf of any third party with an interest in the package. If there is a conflict between the Service Guide and this Airbill, the Service Guide will control. No one is authorized to change the terms of our Agreement.

Responsibility For Packaging And Completing Airbill You are responsible for adequately packaging your goods and properly filling out this Airbill. If you omit the number of packages and/or weight per package, our billing will be based on our best estimate of the number of packages we received and/or an estimated "default" weight per package as determined by us.

Responsibility For Payment Even if you give us different payment instructions, you will always be primarily responsible for all delivery costs, as well as any cost we incur in either returning your package to you or warehousing it pending disposition.

Limitations On Our Liability And Liabilities Not Assumed

• Our liability in connection with this shipment is limited to the lesser of your actual damages or \$100, unless you declare a higher value, pay an additional charge, and document your actual loss in a timely manner. You may pay an additional charge for each additional \$100 of declared value. The declared value does not constitute, nor do we provide, cargo liability insurance.

• In any event, we will not be liable for any damage, whether direct, incidental, special, or consequential in excess of the declared value of a shipment, whether or not Federal Express had knowledge that such damages might be incurred including but not limited to loss of income or profits.

• We won't be liable:

- for your acts or omissions, including but not limited to improper or insufficient packing, securing, marking, or addressing, or those of the recipient or anyone else with an interest in the package.
- if you or the recipient violates any of the terms of our Agreement.
- for loss or damage to shipments of prohibited items.
- for loss, damage, or delay caused by events we cannot control, including but not limited to acts of God, perils of the air, weather conditions, acts of public enemies, war, strikes, civil commotions, or acts of public authorities with actual or apparent authority.

Declared Value Limits

- The highest declared value allowed for a FedEx Envelope and FedEx Pak shipment is \$500.
- For other shipments, the highest declared value allowed is \$50,000 unless your package contains items of extraordinary value, in which case the highest declared value allowed is \$500.
- Items of extraordinary value include shipments containing such items as artwork, jewelry, furs, precious metals, negotiable instruments, and other items listed in our Service Guide.
- You may send more than one package on this Airbill and fill in the total declared value for all packages, not to exceed the \$100, \$500, or \$50,000 per package limit described above. (Example: 5 packages can have a total declared value of up to \$250,000.) In that case, our liability is limited to the actual value of the package(s) lost or damaged, but may not exceed the maximum allowable declared value(s) or the total declared value, whichever is less. You are responsible for proving the actual loss or damage.

Filing A Claim YOU MUST MAKE ALL CLAIMS IN WRITING and notify us of your claim within strict time limits set out in the current Service Guide.

You may call our Customer Service department at 1-800-Go.FedEx® 800.463.3339 to report a claim; however, you must still file a timely written claim.

Within 90 days after you notify us of your claim, you must send us all the information you have about it. We aren't obligated to act on any claim until you have paid transportation charges, and you may not deduct the amount of your claim from those charges.

If the recipient accepts your package without noting any damage on the delivery record, we will assume the package was delivered in good condition. For us to process your claim, you must make the original shipping cartons and packing available for inspection.

Right To Inspect We may, at our option, open and inspect your packages before or after you give them to us to deliver.

Right Of Rejection We reserve the right to reject a shipment when such shipment would be likely to cause delay or damage to other shipments, equipment, or personnel; or if the shipment is prohibited by law; or if the shipment would violate any terms of our Airbill or our current Service Guide.

C.O.D. Services C.O.D. SERVICE IS NOT AVAILABLE WITH THIS AIRBILL. If C.O.D. Service is required, please use a Federal Express C.O.D. Airbill.

Air Transportation Tax Included A federal excise tax when required by the Internal Revenue Code on the air transportation portion of this service, if any, is paid by us.

Money-Back Guarantee In the event of untimely delivery, Federal Express will, at your request and with some limitations, refund or credit all transportation charges. See current Service Guide for more information.

Explore Registrations			
Reg Number:	71693-R	Reg. Type:	Product Registration - Section 3
Name:	Aspergillus Flavus AF36		Status: Under Review (14-Aug-2002)
View Registration Details			
(No New Receipts)			
S	Submission Type	OPP Rec'd Date	Resubmission
Description			
<div> <div> Decisions .. <ul style="list-style-type: none"> Data Requirements <ul style="list-style-type: none"> D: 206011; 71693-R;157;DATA WAIVER REQUE D: 206010; 71693-R;194;ACTION INITIATED BY <ul style="list-style-type: none"> DP 283761,BPPD/IO, Admin Due Date: 29- <ul style="list-style-type: none"> PC Code:006456 S: 630863 3/11/03; Correspondence; 71693 D: 206009; 71693-R;194;ACTION INITIATED BY <ul style="list-style-type: none"> DP 283777,BPPD/IO; Admin Due Date: 29- <ul style="list-style-type: none"> S: 630862 3/11/03; Correspondence; 71693 D: 206008; 71693-R;152;NEW INGREDIENT,NE D: 206007; 71693-R;010;NEW INGREDIENT SC D: 206006; 71693-R;010;NEW INGREDIENT SC </div> <div> Decision Sequence: 206010 Action: 194 ACTION INITIATED BY THE AGENCY;DATA REQUIRED Number: 71693-R Name: Aspergillus Flavus AF36 Decision Status: PENDING (11-Mar-2003) Organization Owner: BPPD/IO Team Owner: RM 90 Calculated Due Date: 07-Sep-2003 Received by Risk Manager: 11-Mar-2003 Active Days Elapsed: Priority Points: Comments: Formal submission of acute health effects data waivers </div> </div>			

S 620798 Action code 010 - Newborn Screening
 624885 010 - Lactate pulmonary
 acute pulmonary hypertension

Explore Registrations

Reg Number: 71693-R Reg. Type: Product Registration - Section 3 Status: Under Review (14-Aug-2002)
 Name: Aspergillus Flavus AF36 <View Registration Details>

(No New Receipts)

S.	Submission Type	OPP Rec'd Date	Resubmission	Description
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- Decisions...
- Data Requirements
 - D: 206011; 71693-R;157;DATA WAIVER REQUEST
 - D: 206010; 71693-R;194;ACTION INITIATED BY DP 288781;BPPD / IO; Admin Due Date: 29-PC Code:006456
 - S: 630863 3/11/03; Correspondence; 71693
 - D: 206009; 71693-R;194;ACTION INITIATED BY DP 288777;BPPD / IO; Admin Due Date: 29-S: 630862 3/11/03; Correspondence; 71693
 - D: 206008; 71693-R;152;NEW INGREDIENT;NEW REG
 - D: 206007; 71693-R;010;NEW INGREDIENT SC
 - D: 206006; 71693-R;010;NEW INGREDIENT SC

Decision Sequence: 205017

Action: 157; DATA WAIVER REQUEST;NEW INGREDIENT;NEW REG

Number: 71693-R

Name: Aspergillus Flavus AF36

Decision Status: COMPLETED (15-May-2003)

Organization Owner: BPPD / IO

Team Owner: RM 90

Calculated Due Date: 08-Aug-2003 Received by Risk Manager: 11-Mar-2003

Active Days Elapsed: 12 Editable Due Date:

Priority Points:

Comments: DWY requests eco effects

Explore Registrations

Reg Number: 71693-R Reg. Type: Product Registration - Section 3 Status: Under Review (14-Aug-2002)
 Name: Aspergillus Flavus AF35 <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
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Decisions...

- Data Requirements
- D: 205011; 71693-R;157;DATA WAIVER REQUE
- D: 206010; 71693-R;194;ACTION INITIATED BY
- DP 288781;BPPD/ IO; Admin Due Date: 29-Jul-2003
- PC Code:006456
- S: 630863 3/11/03; Correspondence; 71693
- D: 206009; 71693-R;194;ACTION INITIATED BY
- DP 288777;BPPD/ IO; Admin Due Date: 29-Jul-2003
- S: 630862 3/11/03; Correspondence; 71693
- D: 206008; 71693-R;152;NEW INGREDIENT;NE
- D: 206007; 71693-R;010;NEW INGREDIENT SC
- D: 206006; 71693-R;010;NEW INGREDIENT SC

DP: 288781

Ingredient: Aspergillus flavus 36 colonized wheat seed

Expedite: ☐ Yes ☒ No

Beans: 1

DPKG Title:

Data Package Dates: Admin Due Date: 29-Jul-2003

Sent to:

Sent From:

Organization: BPPD / IO

BPPD / IO

Team: RM 90

RM 90

Reviewer: CETSITY

SBACCHUS

Label?: ☒ Yes ☐ No

CSF?: ☒ Yes ☐ No

Instructions: Please confirm that the justifications for the data waiver requests submitted for the acute health effects studies are acceptable for the Sec. 3c registration of A. flavus AF35 for use in AZ and TX. If there are

Explore Registrations

Reg Number: 71693-R Reg. Type: Product Registration - Section 3 Status: Under Review (14-Aug-2002)
 Name: Aspergillus Flavus AF36 <View Registration Details>

(No New Receipts)

S.	Submission Type	OPP Rec'd Date	Resubmission	Description
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- ...Decisions...
 - Data Requirements
 - D: 206011; 71693-R;157;DATA WAIVER REQUE
 - D: 206010; 71693-R;194;ACTION INITIATED BY
 - DP 288777;BPPD / IO; Admin Due Date: 29-Jul-2003
 - PC Code:006456
 - S: 630863 3/11/03; Correspondence; 71693
 - D: 206009; 71693-R;194;ACTION INITIATED BY
 - DP 288777;BPPD / IO; Admin Due Date: 29-Jul-2003
 - S: 630862 3/11/03; Correspondence; 71693
 - D: 206008; 71693-R;152;NEW INGREDIENT,IVE
 - D: 206007; 71693-R;010;NEW INGREDIENT SC
 - D: 206006; 71693-R;010;NEW INGREDIENT SC

DP: 288777

Ingredient: Aspergillus flavus 36 colonized wheat seed

Expedite: ☐ Yes ☒ No Beans: 1

DPKG Title:

Data Package Dates: Admin Due Date: 29-Jul-2003

Sent to	Sent From
Organization: BPPD / IO	BPPD / IO
Team: RM/90	RM 90
Reviewer: GTOMMAT	SBACCHUS
Label?: <input checked="" type="radio"/> Yes <input type="radio"/> No	CSF?: <input checked="" type="radio"/> Yes <input type="radio"/> No

Instructions: Please review the data submitted to demonstrate the efficacy of AF36 on cotton in AZ and TX. The registrant is considering efficacy as displacement of the toxigenic strain of A. flavus by the atoxigenic strain A. flavus.

Explore Registrations

Reg Number: 71693-R Reg. Type: Product Registration - Section 3 Status: Under Review (14-Aug-2002)
 Name: Aspergillus Flavus AF36 <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description

- Decisions...
 - Data Requirements
 - D: 206011; 71693-R;157;DATA WAIVER REQUE
 - D: 206010; 71693-R;194;ACTION INITIATED BY
 - DP 288781;BPPD / IO; Admin Due Date: 29-
 - PC Code:006456
 - S: 630863 3/11/03; Correspondence; 71693
 - D: 206009; 71693-R;194;ACTION INITIATED BY
 - DP 288777;BPPD / IO; Admin Due Date: 29-
 - S: 630862 3/11/03; Correspondence; 71693
 - D: 206008; 71693-R;152;NEW INGREDIENT,NE
 - D: 206007; 71693-R;010;NEW INGREDIENT SC
 - D: 206006; 71693-R;010;NEW INGREDIENT SC

S: 630862 Reg #: 71693-R

Submission Type: Correspondence

Resubmission? ☐ Yes ☒ No

Decision #: 206009; 194;ACTION INITIATED BY THE AGENCY;DATA REG

Submitter Company: ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

Application Date: 07-Mar-2003

OPP Received Date: 11-Mar-2003 Date Sent to Risk manager: 11-Mar-2003

Studies Included? ☐ Yes ☒ No Fast Track? ☐ Yes ☒ No

Form A Signed? ☐ Yes ☐ No ☒ None Date:

Form B Signed? ☐ Yes ☐ No ☒ None Date:

Reviewer: Bacchus, Shanaz

Received DT: 11-Mar-2003 Editable Due DT:

Admin Due DT: 07-Sep-2003 Response: 11-Mar-2003

Priority Weight: Priority Points:

Comments: Efficacy data for AF36 on cotton In TX

Reg. Number: **71693-R** Reg. Type: **Product Registration - Section 3** Status: **Under Review (14-Aug-2002)**
 Name: **Aspergillus Flavus AF36** [View Registration Details](#)

(No New Receipts)				
S	Submission Type	OPP Rec'd Date	Resubmission	Description

- Decisions...
 - Data Requirements
 - D: 206011; 71693-R;157;DATA WAIVER REQUE
 - DP 288782;BPPD/IO; Admin Due Date: 24-**
 - S: 630867 3/11/03; New Registration; 71693
 - D: 206010; 71693-R;194;ACTION INITIATED BY
 - D: 206009; 71693-R;194;ACTION INITIATED BY
 - D: 206008; 71693-R;152;NEW INGREDIENT;NE
 - D: 206007; 71693-R;010;NEW INGREDIENT SC
 - D: 206006; 71693-R;010;NEW INGREDIENT SC

DP: **288782**
 Ingredient: **Aspergillus flavus 36 colonized wheat seed**
 Expedite: ☐ Yes ☒ No Beans:
 DPKO Title:
 Data Package Dates: **Admin Due Date: 24-Jun-2003**

Sent to:	Sent From:
Organization: BPPD/IO	BPPD/IO
Team: RM 90	RM 90
Reviewer: GTOMMAT	SBACCHUS

 Label?: ☒ Yes ☐ No CSF?: ☒ Yes ☐ No
 Instructions: **Please determine whether the justifications for waiving ecological effects data are acceptable (Section 2 of this submission). If there are deficiencies in the justifications, please state what steps/further action**

Reg Number: **71693-R** Reg. Type: **Product Registration - Section 3** Status: **Under Review (14-Aug-2002)**
 Name: **Aspergillus Flavus AF36** [View Registration Details](#)

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
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- Decisions...
- Data Requirements
 - D: 206011; 71693-R;157;DATA WAIVER REQUE
 - DP 288782,BPPD / IO; Admin Due Date: 24-
 - S: 630867 3/11/03; New Registration: 71693
 - D: 206010; 71693-R;194;ACTION INITIATED BY
 - D: 206009; 71693-R;194;ACTION INITIATED BY
 - D: 206008; 71693-R;152;NEW INGREDIENT;NE
 - D: 206007; 71693-R;010;NEW INGREDIENT SC
 - D: 206006; 71693-R;010;NEW INGREDIENT SC

S: **630867** Reg #: **71693-R**
 Submission Type: **New Registration**
 Resubmission?: ☐ Yes ☒ No
 Decision #: **206011; 157; DATA WAIVER REQUEST; NEW INGREDIENT; NE**
 Submitter Company: **ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL**
 Application Date: **07-Mar-2003**
 OPP Received Date: **11-Mar-2003** Date Sent to Risk manager: **11-Mar-2003**
 Studies Included?: ☐ Yes ☒ No Fast Track?: ☐ Yes ☒ No
 Form A Signed? ☐ Yes ☐ No ☒ None Date:
 Form B Signed? ☐ Yes ☐ No ☒ None Date:
 Reviewer: **Bacchus, Shanaz**
 Received DT: **11-Mar-2003** Editable Due DT:
 Admin Due DT: **08-Aug-2003** Response: **0, 11-Mar-2003**
 Priority Weight: Priority Points:
 Comments: **DW requests eco effects**

Reg Number: 71693-R

Reg. Type: Product Registration - Section 3

Status: Under Review (14-Aug-2002)

Name: Aspergillus Flavus AF36

[<View Registration Details>](#)

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
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Decisions...

Data Requirements

D: 206011; 71693-R;157;DATA WAIVER REQUE

D: 206011; 71693-R;157;DATA WAIVER REQUE

D: 206011; 71693-R;157;DATA WAIVER REQUE

D: 206011; 71693-R;157;DATA WAIVER REQUE

D: 206011; 71693-R;157;DATA WAIVER REQUE

D: 206011; 71693-R;157;DATA WAIVER REQUE

D: 206011; 71693-R;157;DATA WAIVER REQUE

D: 206011; 71693-R;157;DATA WAIVER REQUE

D: 206011; 71693-R;157;DATA WAIVER REQUE

Decision Sequence: 206009

Action: 194 ACTION INITIATED BY THE AGENCY DATA REQUIRED

Number: 71693-R

Name: Aspergillus Flavus AF36

Decision Status: PENDING (11-Mar-2003)

Organization Owner: BPPD / IO

Team Owner: RM 99

Calculated Due Date: 07-Sep-2003

Received by Risk Manager: 11-Mar-2003

Active Days Elapsed:

Editable Due Date:

Priority Points:

Comments: Efficacy data for AF36 on cotton in TX

Reg Number: 71693-R Reg. Type: Product Registration - Section 3 Status: Under Review (14-Aug-2002)
Name: Aspergillus Flavus AF36 <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
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...Decisions...

- Data Requirements
- D: 206011; 71693-R;157;DATA WAIVER REQUE
- DP 288782;BPPD / IO; Admin Due Date: 24-
- S: 630867 3/11/03; New Registration; 71693
- D: 206010; 71693-R;194;ACTION INITIATED BY
- D: 206009; 71693-R;194;ACTION INITIATED BY
- D: 206008; 71693-R;152;NEW INGREDIENT;NE**
- D: 206007; 71693-R;010;NEW INGREDIENT SC
- D: 206006; 71693-R;010;NEW INGREDIENT SC

Decision Sequence: 206008

Action: 152 NEW INGREDIENT;NEW REGISTRATION;PROPOSED TE

Number: 71693-R

Name: Aspergillus Flavus AF36

Decision Status: COMPLETED (16-Apr-2003)

Organization Owner: BPPD / IO:

Team Owner: RM 90

Calculated Due Date: 05-Apr-2003 Received by Risk Manager: 07-Nov-2002

Active Days Elapsed: 20

Editable Due Date:

Priority Points:

Comments: scd: honeybee, avian inhalation, plovers

Reg Number: 71693-R Reg. Type: Product Registration - Section 3 Status: Under Review (14-Aug-2002)
 Name: Aspergillus Flavus AF36 <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
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Decisions...

- Data Requirements
- D: 206011; 71693-R;157;DATA WAIVER REQUE
- DP 288782;BPPD / IO; Admin Due Date: 24
- S: 630867 3/1/03; New Registration; 71693
- D: 206010; 71693-R;194;ACTION INITIATED BY
- D: 206009; 71693-R;194;ACTION INITIATED BY
- D: 206008; 71693-R;152;NEW INGREDIENT;NE
- D: 206007; 71693-R;010;NEW INGREDIENT SC**
- D: 206006; 71693-R;010;NEW INGREDIENT SC

Decision Sequence: 206007

Action: DID: NEW INGREDIENT SCREENING

Number: 71693-R

Name: Aspergillus Flavus AF36

Decision Status: PENDING (07-Nov-2002)

Organization Owner: BPPD / IO

Team Owner: RM 90

Calculated Due Date: 16-May-2003 Received by Risk Manage: 07-Nov-2002

Active Days Elapsed:

Editable Due Date:

Priority Points:

Comments: acute pulmonary hypersensitivity

Reg Number: 71693-R Reg. Type: Product Registration - Section 3 Status: Under Review (14-Aug-2002)

Name: Aspergillus Flavus AF36

<View Registration Details>

(No New Receipts)

S.	Submission Type	OPP Rec'd Date	Resubmission	Description
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...Decisions...

Data Requirements

D: 206011; 71693-R;157;DATA WAIVER REQUE

DP 288782;BPPD / IO; Admin Due Date: 24

S: 630867 3/11/03; New Registration; 71693

D: 206010; 71693-R;194;ACTION INITIATED BY

D: 206009; 71693-R;194;ACTION INITIATED BY

D: 206008; 71693-R;152;NEW INGREDIENT;NE

D: 206007; 71693-R;010;NEW INGREDIENT SC

D: 206006; 71693-R;010;NEW INGREDIENT SC

Decision Sequence: 206006

Action: 010 NEW INGREDIENT SCREENING

Number: 71693-R

Name: Aspergillus Flavus AF36

Decision Status: PENDING (14-Aug-2002)

Organization Owner: BPPD / IO

Team Owner: RM 90

Calculated Due Date: 12-Dec-2002

Received by Risk Manager: 22-Aug-2002

Active Days Elapsed:

Editable Due Date:

Priority Points:

Comments:

Current Data Package is LOCKED

DP Sequence: 288781 Expedite: ☐ Yes ☒ No Label: ☒ Yes ☐ No CSF: ☒ Yes ☐ No

Bean Count: 1

Date Package Title:

Parent DP #:

Instructions: Please confirm that the justifications for the data waiver requests submitted for the acute health effects studies are acceptable for the Sec. 3c registration of A. flavus AF36 for use in AZ and TX. If there are deficiencies in this request, please state clearly what data/justification must be submitted to satisfy the deficiency.

Unlock Data Pkg

Bean Sheet

Data Package Comments

Sent To Sent From DP Dates MRDS Sub-DP DP Ingredients DP Contract Receipts

Organization Name: BPPD / IO

Date Received: 11-Mar-2003

Date Completed: 22-May-2003

Team Name	Team Description	Date Received	Date Completed
RM 90	Biologicals & Pollution Prevention Division, PM Team 90	11-Mar-2003	22-May-2003

Team(s) Linked

Staff Name	Est. Hrs	Actual Hrs	Date Received	Date Completed
Etsitty, Carl			11-Mar-2003	22-May-2003

Staff Member(s) Linked

Viewing Record 1 of 1

Current Data Package is LOCKED

DP Sequence: 286780 Expedite: ☐ Yes ☒ No Label: ☒ Yes ☐ No CSF: ☒ Yes ☐ No

Bean Count: 1

Data Package Title:

Parent DP #:

Instructions: Please do a secondary review of data for AF36 effects on honeybee in cotton fields. If there are any data deficiencies, describe what data are required to satisfy them.
Thanks.
shawn

Unlink Data Pkg
Bean Sheet

Data Package Comments

☒ Sent To ☒ Sent From ☒ DP Dates ☒ MRIDS ☒ Sub-DP ☒ DP Ingredients ☒ DP Contract ☒ Receipts

Organization Name: BPPD / 10

Date Received: 06-Mar-2003

Date Completed: 29-Apr-2003

Team Name	Team Description	Date Received	Date Completed
<input checked="" type="checkbox"/> RMI 90	Biologicals & Pollution Prevention Division, Pmt Team 90	06-Mar-2003	29-Apr-2003

Team(s) Linked

Staff Name	Est. Hrs.	Actual Hrs.	Date Received	Date Completed
<input checked="" type="checkbox"/> Reynolds, Alan			06-Mar-2003	29-Apr-2003

Staff Member(s) Linked

Viewing Record 1 of 1

Current Data Package is LOCKED

DP Sequence: 286705 Expedite: ☐ Yes ☒ No Label: ☒ Yes ☐ No CSF: ☒ Yes ☐ No

Bean Count: 1

Date Package Title:

Parent DP #:

Instructions:

Please review the following for use of Aspergillus flavus/atoxigenic strain AF36 for use on cotton to displace the toxigenic strain.
457981-01: Acute pulmonary tox/path in rat. This study was discontinued because of the adverse effects of Tween. The other 2 studies were conducted to replace this study.

Unlock Data Pkg

Bean Sheet

Data Package Comments

Sent To

Sent From

DP Dates

MRIDS

Sub-DP

DP Ingredients

DP Contract

Receipts

Organization Name: BPPD / ID

Date Received: 07-Nov-2002

Date Completed: 02-Apr-2003

Team Name	Team Description	Date Received	Date Completed
RM 90	Biologicals & Pollution Prevention Division, PM Team 90	07-Nov-2002	02-Apr-2003

Team(s) Linked

Staff Name	Est. Hrs.	Actual Hrs.	Date Received	Date Completed
Etsitty, Carl			07-Nov-2002	02-Apr-2003

Staff Member(s) Linked

Viewing Record 1 of 1

Your Data Package is LOCKED

DP Sequence: 286705 Expect: ☒ Yes ☐ No Label: ☒ Yes ☐ No CSF: ☒ Yes ☐ No

Bean Count: 1

Data Package Title:

Link to Data Pkg

Bean Sheet

Parent DP #:

Instructions: Please review the following for use of Aspergillus niger (ATCC 26911) strain AP36 for use on cotton to displace the toxigenic strain.
457981-01: Acute pulmonary toxipath in rat. This study was discontinued because of the adverse effects of Tween. The other 2 studies were conducted to replace this study.

Data Package Comments

☒ Sent To ☒ Sent From ☒ DP Dates ☒ MIRDS ☒ Sub-DP ☒ DP Ingredients ☒ DP Contract ☒ Receipts

Organization Name: BPPD / IO

Date Received: 07-Nov-2002

Date Completed: 02-Apr-2003

Team Name	Team Description	Date Received	Date Completed
RM 90	Biologicals & Pollution Prevention Division, RM Team 90	07-Nov-2002	02-Apr-2003

Team(s) Linked

Staff Name	Est. Hrs.	Actual Hrs.	Date Received	Date Completed
Essity, Carl			07-Nov-2002	02-Apr-2003

Staff Member(s) Linked

Viewing Record 1 of 1

Current Data Package is LOCKED

DP Sequence: 285708 Expedite: ☐ Yes ☒ No Label: ☒ Yes ☐ No CSF: ☒ Yes ☐ No

Bean Count: 1

Data Package Title:

Parent DP #:

Instructions: Please review the following for use of Aspergillus flavus, toxigenic strain AF36 on cotton in AZ and TX.

457981-01 Tox/path to bobwhite quail

457391-02 Honey bee study of AF36 on cotton

Unlock DataPkg

Bean Sheet

Data Package Comments

Sent To

Sent From

DP Dates

MRIDS

Sub-DP

DP Ingredients

DP Contract

Receipts

Organization Name: BPPD /10

Date Received: 07-Nov-2002

Date Completed: 15-May-2003

Team Name	Team Description	Date Received	Date Completed
RM 90	Biologicals & Pollution Prevention Division, PM Team 90	07-Nov-2002	15-May-2003

Team(s) Linked

Staff Name	Est. Hrs.	Actual Hrs.	Date Received	Date Completed
Tominatsu, Gail			13-Feb-2003	15-May-2003

Staff Member(s) Linked

Viewing Record 1 of 1

Current Data Package is LOCKED

DP Sequence: 288781 Expedite: ☐ Yes ☒ No Label: ☒ Yes ☐ No CSF: ☒ Yes ☐ No

Bean Count: 1

Data Package Title:

Parent DP #:

Instructions: Please confirm that the justifications for the data waiver requests submitted for the acute health effects studies are acceptable for the Sec. 3c registration of A. flavus AF36 for use in AZ and TX. If there are deficiencies in this request, please state clearly what data/justification must be submitted to satisfy the deficiency.

Unlock Data Pkg

Bean Sheet

Data Package Comments

☒ Sent To ☒ Sent From ☒ DP Dates ☒ MRIDS ☒ Sub-DP ☒ DP Ingredients ☒ DP Contract ☒ Receipts

Organization Name: BPPD / IO

Date Received: 11-Mar-2003

Date Completed: 22-May-2003

Team Name	Team Description	Date Received	Date Completed
RM 90	Biologicals & Pollution Prevention Division, PM Team 90	11-Mar-2003	22-May-2003

Team(s) Linked

Staff Name	Est. Hrs.	Actual Hrs.	Date Received	Date Completed
Eteitty, Carl			11-Mar-2003	22-May-2003

Staff Member(s) Linked

Viewing Record 1 of 1

Data Package Information for D: 200111; 71693-R; 157 DATA WAIVER? REQUE...

Current Data Package is LOCKED

DP Sequence: 288782 Expedite: ☐ Yes ☒ No Label: ☒ Yes ☐ No CSF: ☒ Yes ☐ No

Bean Count: 1 Data Package Title:

Parent DP #:

Instructions: Please determine whether the justifications for waiving ecological effects data are acceptable (Section 2 of this submission). If there are deficiencies in the justifications, please state what steps/further action the company needs to take to fulfill data requirements.
Thanks,

Unlock Data Pkg

Bean Sheet

Data Package Comments

Sent To Sent From DP Dates MRIDS Sub-DP DP Ingredients DP Contract Receipts

Organization Name: BPPD / IO

Date Received: 11-Mar-2003

Date Completed: 15-May-2003

Team Name	Team Description	Date Received	Date Completed
RM 90	Biologicals & Pollution Prevention Division, PM Team 90	11-Mar-2003	15-May-2003

Team(s) Linked

Staff Name	Est. Hrs.	Actual Hrs.	Date Received	Date Completed
Tomimatsu, Gail			11-Mar-2003	15-May-2003

Staff Member(s) Linked

Viewing Record 1 of 1

***Current Data Package is LOCKED**

DP Sequence: 288780 Expedite: ☐ Yes ☒ No Label: ☒ Yes ☐ No CSF: ☒ Yes ☐ No

Bean Count: 1

Data Package Title:

Parent DP #:

Instructions: Please do a secondary review of data for AF36 effects on honeybee in cotton fields. If there are any data deficiencies, describe what data are required to satisfy them.

Thanks.

shawn

Unlock Data Pkg

Bean Sheet

Data Package Comments

☒ Sent To ☒ Sent From ☒ DP Dates ☒ MRDS ☒ Sub-DP ☒ DP Ingredients ☒ DP Contract ☒ Receipts

Organization Name: BPPD / IO

Date Received: 06-Mar-2003

Date Completed: 29-Apr-2003

Team Name	Team Description	Date Received	Date Completed
<input checked="" type="checkbox"/> RM 90	Biologicals & Pollution Prevention Division, PM Team 90	06-Mar-2003	29-Apr-2003

Team(s) Linked

Staff Name	Est. Hrs.	Actual Hrs.	Date Received	Date Completed
<input checked="" type="checkbox"/> Reynolds, Alan			06-Mar-2003	29-Apr-2003

Staff Member(s) Linked

Viewing Record 1 of 1

BPPD PRAT ACTION CODING FORM

FOR PAPER SUBMISSION

REGISTRANT/COMPANY NAME:

Arizona Cotton Research + Protection Council

Fast Track: Yes ☐ No ☒

Reviewer Alan Bacchus

Assigned by J. Downing

EPA REG./FILE SYMBOL 71693-R

(Note: If Fast Track, you may

need to change Reviewer's

Name in PRAT.)

ACTION CODE 101

(New A.I./EUP'S/Tolerances: Yes ☒ No ☐)

DATE OF APPLICATION 5-23-03

EPA RECEIVED DATE 5-28-03

BPPD RECEIVED DATE 5-29-03

SUBMISSION BARCODE 5735832

ASSIGNED IN PRAT: Yes ☐ No ☒ entered in OPPIN

COMPLETED BY J. Downing DATE 5-29-03

LOGGED IN BRATS: Yes ☒ No ☐ DATE 5-29-03 COMPLETED BY J. Downing

RAL RECEIVED _____ DATE _____

(RAL number)

FINAL ACTION

RESPONSE CODE: _____

RESPONSE DATE: _____

MOS: _____ (1) Cite All
_____ (2) Not Applicable
_____ (3) Selective

CRP	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Restricted Use	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Manufacturing Use	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Exclusive Use	Yes <input type="checkbox"/>	No <input type="checkbox"/>



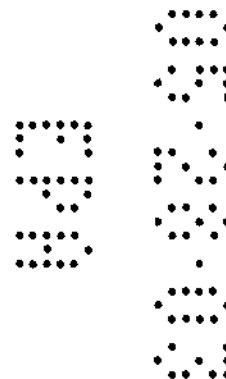
ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

Dennis Szuhay, Acting Chief
Microbial and Plant Incorporated Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 910, Crystal Mall 2
Arlington Virginia, 22202
(703) 308-8260

May 23, 2003

RE: Pending Section 3 Registration-*Aspergillus flavus* AF36
EPA Reg. No. 71693-R; Active Ingredient # 006546
Pending Pesticide Petition # 8E5001
RAL Shanaz Bacchus (703)308-8097



Dear Dennis:

This is in response to your letter dated May 22, 2003 (attached) notifying us about our active ingredient *Aspergillus flavus* AF36 eligibility for a conditional Section 3(c)7(C) registration on cotton in AZ and TX. We are hereby committing to provide the following data within the time frames you requested as shown below as conditions of registration:

1. Guidelines 151-10 through 151-16 (OPPTS Gdln 885.1300): Product Identity

Analyses of 5 batches is required at production and must include data relevant to certification of limits, detection, identification, enumeration and rejection limits of metabolites and potential human pathogens (bacterial and fungal) using routine quality control and assurance methods to be implemented for large scale production. Batch analysis must also include viability and storage stability data. All batches containing human pathogens above regulatory levels must be destroyed. A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36. Data to remove this condition of registration must be submitted within 2.5 years of the conditional registration. If at any time the formulation, manufacturing process or quality control methods change, you must submit appropriate relevant data to amend the conditional registration of this microbial active ingredient.

Our understanding of "enumeration and rejection limits of metabolites" is that we will continue to analyze for aflatoxin in the working culture by TLC in all batches as already described in MRID 44626101 which is prior to inoculating the wheat. We agree to do the analysis for aflatoxin as a post production analysis only as part of the five batch analysis, but there will not be any post production analysis for aflatoxin as part of the routine quality control procedure.

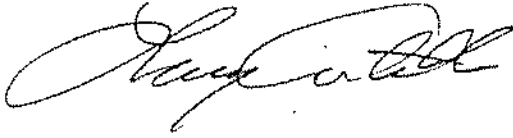
Similarly, our understanding of "A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36" means that we will continue to utilize vegetative compatibility grouping as a test prior to and after production. We agree to use a DNA based confirmatory method only on the 5 batch analysis, but not as part of the routine quality control procedure.

2. Efficacy data are required from a large scale field trial in TX to confirm the bridging of data from Arizona to Texas and to demonstrate that *Aspergillus flavus* AF36 reduces aflatoxin-producing strains of *Aspergillus flavus*

A table clarifying these data requirements is below. Through communication with Shanaz Bacchus, we understand that you already have the appropriate final draft label for stamping. We understand that further data may be required for different formulations and application methods and other use sites, on a case by case basis, if such amendments ensue during this conditional registration.

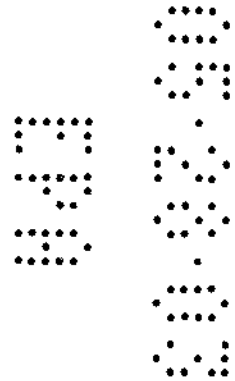
Data required as a condition of Registration of <i>Aspergillus flavus</i> AF36			
Guideline	Title of Study	Data Required	Due Date
885.1300 151B-12	Discussion of Formation of Unintentional Ingredients	Formation of unintentional ingredients, human pathogen and metabolite identification and quantification (including aflatoxin quantification).	During production of 5 batches or 2.5 years after conditional registration date.
*885.1400 151B-13	Analysis of Samples	5 batch analysis to include viability and storage stability data.	During production of 5 batches or 2.5 years after conditional registration date.
*885.1500 151B-15	Certification of limits	Standard data requirement for production batches.	During production of 5 batches or 2 years after conditional registration date.
Non-guideline: required for public health hazard	Efficacy/Product Performance	Efficacy/Product Performance data to demonstrate the reduction of toxigenic strains by <i>A. flavus</i> AF36 in Texas.	2.5 years after conditional registration date.

Sincerely,



Larry Antilla,
Staff Director
Arizona Cotton Research and Protection Council

CC: Shanaz Bacchus, BPPD, USEPA
Phil Hutton, BPPD, USEPA
Janet Andersen, BPPD, USEPA
Peter Cotty, USDA-ARS
Phil Wakelyn, National Cotton Council



ROUTING AND TRANSMITTAL SLIP

Date

6/3/03

TO: (Name, office symbol, room number,
building, Agency/ Post)

Initials

Date

1.

Christina Gassu

2.

3.

4.

5.

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

Please type + return to
me
Thanks

DO NOT use this form as a RECORD of approvals, concurrences, disposals,
clearances, and similar actions

FROM: (Name, org. symbol, Agency/ Post)

Shawn

Room No. — Bldg.

CM2 910W 38

Phone No.

308-8097

NSN 7540-00-935-5862
5041-103



OPTIONAL FORM 41 (Rev. 1-94)
Prescribed by GSA
UNICOR FPI - SST



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

Memorandum

SUBJECT: Cost of Publishing Documents in the Federal Register

FROM: John A. Richards, Director, OPPTS Federal Register Staff (7104T)

TO: OPPTS Document Drafters

In view of the limited amount of money that will be available for publishing documents in the Federal Register in the current fiscal year, the OPPTS Federal Register Staff is cooperating with budget and program personnel by keeping you informed of printing costs.

This document when prepared with electronic encoding will bill as follows:

Document OPPTS No.: 03P-0854

Pages/columns: 17

Approximate cost: \$ 1,853

We are furnishing this information so that you will be better able to allocate your funds during the remainder of the fiscal year. Unless a deliberate decision is made to withhold this document from publication, it will be forwarded automatically for publication upon its receipt after signature by my office. A hold can be placed on actual publication by calling the Federal Register Staff on (566-1580) prior to signature, and providing alternate instructions.

For OPPTS FR Staff Use Only

Expedited (Check One)		Templated Documents				Shell Documents				Adj. Value
		Text Pages		Tables		Text Pages		Tables		
		Initial Text	Revised Text	Initial Text	Revised Text	Initial Text	Revised Text	Initial Text	Revised Text	
Yes	No									
	✓	17								

DP BARCODE: D288781

CASE: 062458
SUBMISSION: S630863

DATA PACKAGE RECORD
BEAN SHEET

DATE: 05/22/03
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 194 ACTN INI BY AGCY-ADDL REQ
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 03/11/03 DUE OUT DATE: 09/07/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288781 EXPEDITE: N DATE SENT: 03/11/03 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001

	CSF: Y		LABEL: Y	
ASSIGNED TO		DATE IN	DATE OUT	ADMIN DUE DATE: 07/29/03
DIV : BPPD		03/11/03	/ /	NEGOT DATE: / /
BRAN: BPPD-IO		03/11/03	/ /	PROJ DATE: / /
SECT: IO		03/11/03	/ /	
REVR : CETSITTY		03/11/03	/ /	
CONTR:		/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Please confirm that the justifications for the data waiver requests submitted for the acute health effects studies are acceptable for the Sec. 3c registration of A. flavus AF36 for use in AZ and TX. If there are deficiencies in this request, please state clearly what data/justification must be submitted to satisfy the deficiency.
Thanks,
shawn

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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May 26, 2003

Table 4: Data required

Guideline	Title of Study	Data required	Date due
*885.1300 151B-12	Discussion of Formation of Unintentional Ingredients	Human pathogen and metabolite identification and quantification (including aflatoxin quantification by HPLC).	During production of 5 batches or 2 years after conditional registration date.
*885.1400 151B-13	Analysis of Samples	5 batch analysis to include another method apart from VCG analysis to identify <i>Aspergillus flavus</i> AF36, viability and storage stability data.	During production of 5 batches or 2.5 years after conditional registration date.
*885.1500 151B-15	Certification of limits	Standard data requirement for production batches.	During production of 5 batches or 2 years after conditional registration date.
Non-guideline: required for public health hazard	Efficacy	Efficacy data to demonstrate the reduction of toxigenic strains by <i>A. flavus</i> AF36 in Texas.	2.5 years after conditional registration date.

*OPPTS Harmonized Guidelines

VII. APPENDICES

APPENDIX A

Table 5 lists the use sites for the product. The registrant must comply with the appropriate labeling requirements before releasing products containing *Aspergillus flavus* AF36 as the active ingredient for shipment.

Table 5: Use Site Conditional registration

Prebloom application by ground or air to cotton in Arizona, Texas.	Official date registered:
--	---------------------------

APPENDIX B - Citations Considered to be part of the Data Base Supporting the
Conditional registration of *Aspergillus flavus* strain AF36.

CITATIONS/BIBLIOGRAPHY

Studies submitted in support of this registration action and Pesticide Petition 8E5001

- 43763400 USDA/ARS and IR-4 (1995) Submission of Product Chemistry, Toxicity, and Risk Data in Support of an Experimental Use Permit for *Aspergillus flavus* AF36. Transmittal of 5 Studies.
- 43763401 Cotty, P. (1995) *Aspergillus flavus* Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p.
- 43763402 Cotty, P. (1995) *Aspergillus flavus* Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p.
- 43763403 Cotty, P.; Hartman, C. (1995) *Aspergillus flavus* Isolate AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for *Aspergillus flavus* for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p.
- 43763404 Cotty, P. (1995) *Aspergillus flavus* Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding No Hypersensitivity: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 4 p.
- 43763405 Cotty, P.; Hartman, C. (1995) *Aspergillus flavus* Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p.
- 43972400 Interregional Research Project No. 4 (1996) Submission of Product Analysis and Toxicology Data in Support of an Experimental Use Permit for *Aspergillus flavus* AF36. Transmittal of 3 Studies.
- 43972401 Cotty, P. (1996) *Aspergillus flavus* Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 1 to MRID No. 43763404: Lab Project Number: PR 52B: 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 6 p.

- 43972402 Cotty, P. (1996) *Aspergillus flavus* Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity: Amendment No. 1 to MRID No. 43763404; Lab Project Number: 52B: PR 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 4 p.
- 43972403 Shelton, L. (1996) Acute Oral Toxicity Study in Rats: (*Aspergillus flavus* AF36): Final Report: Lab Project Number: M96AG84.6G31: MA M96AG84.6G31. Unpublished study prepared by Microbiological Associates, Inc. 59 p.
- 43990000 Interregional Research Project No. 4 (1996) Submission of Product Chemistry Data in Support of the Application for Experimental Use Permit for *Aspergillus flavus* AF36. Transmittal of 1 Study.
- 43990001 Cotty, P. (1996) *Aspergillus flavus* Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process, and Discussion on the Formation of Unintentional Ingredients: Amendment No. 1 to MRID 43763401: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS, Southern Regional Research Center. 6 p.
- 44597000 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of *Aspergillus flavus* isolate AF36 in/on Wheat. Transmittal of 1 Study.
- 44597001 Cotty, P.; Antilla, L. (1998) *Aspergillus flavus* Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p.
- 44626100 Interregional Research Project No. 4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of *Aspergillus flavus* isolate AF36 in/on Cotton. Transmittal of 1 Study.
- 44626101 Cotty, P.; Antilla, L. (1998) *Aspergillus flavus* isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p.

- 44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of *Aspergillus flavus* in/on Cotton. Transmittal of 1 Study.
- 44713701 Cotty, P.; Antilla, L. (1998) *Aspergillus Flavus* isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p.
- 45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of *Aspergillus flavus* Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies.
- 45307201 Cotty, P. (2001) *Aspergillus flavus* Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of *A. flavus*): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.
- 45739100 Interregional Research Project No. 4 (2002) Submission of Toxicity and Exposure Data in Support of the Petition for Tolerance of *Aspergillus flavus* on Cotton. Transmittal of 4 Studies.
- 45739103 Smith, D.; Cotty, P.; Braverman, M.; et al. (2002) *Aspergillus flavus* Isolate AF36: Non-Target Organism and Environmental Safety Information: Lab Project Number: IR-4 PR NO.52B: Unpublished study prepared by Soil & Crop Sciences, Southern Regional Research Center USDA/ARS, Rutgers University and Arizona Cotton Research and Protection Council. 57 p.
- 45739101 Blanchard, E.; Carter, J. (2002) *Aspergillus flavus* AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}
- 45739104 Antilla, L., Cotty, P.; Braverman, M. (2002) *Aspergillus flavus* Isolate AF336: Hypersensitivity Incidents: Lab Project Number: 52B. Unpublished study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.
- 45739102 Mayer, D. (2001) Honey Bee Field Study of *Aspergillus flavus* AF36 in Cotton: Lab Project Number: WSU 00-011. Unpublished study prepared by Washington State University. 30 p. {OPPTS 850.3040, 885.4380}

- 45307202 Cotty, P. (2001) *Aspergillus flavus* Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of *A. flavus*): Lab Project Number:52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.
- 45739101 Blanchard, E.; Carter, J. (2002) *Aspergillus flavus* AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

Federal Register Publications

1. Federal Register: February 28, 1996 (Volume 61, Number 40)][Page 7512-7513]. *Aspergillus Flavus* Isolate AF36; Notice of Filing of a Pesticide Petition
2. Federal Register: June 14, 1996 (Volume 61, Number 116)][Notices] [Page 30235-30236] *Aspergillus flavus* AF 36; Establishment of Temporary Exemption from the Requirement of a Tolerance (expiration May 29, 1999)
4. Federal Register: February 19, 1999 (Volume 64, Number 33)][Page 8358-8360] Notice of Filing of Pesticide Petitions (to amend exemption from tolerance to apply 20,000 acres, extend date to Dec. 2000]
5. Federal Register: May 26, 1999. Extension of temporary exemption from tolerance and amendment to comply with the Food Quality Protection Act (FQPA) of 1996 (Vol. 64, No. 101) [Page 28371-28374]. Extend to 12/30/2000.
6. Federal Register: June 30, 1999 (Volume 64, Number 125)][Page 35049-35051]. *Aspergillus flavus* AF36; Exemption from Temporary Tolerance, Technical Amendment extend to 12/30/2001
7. Federal Register: May 23, 2001. (Volume 66, Number 100)) [Page 28383-28386] *Aspergillus flavus* AF36; Extension of Temporary Exemption From the Requirement of a Tolerance - Final Rule to expire on December 30, 2003.
8. Federal Register: March 25, 2002 (Volume 67, Number 57)][Page 13628-13630] Notice of Filing a Pesticide Petition to Amend An Existing Tolerance for a Certain Microbial Pesticide Chemical in or on Food [PP 5E4575].

9. Federal Register: July 17, 2002 (Volume 67, Number 137)[Page 46884-46888].
Aspergillus flavus AF36; Amendment, Temporary Exemption From the Requirement of a Tolerance expires Dec 30, 2004.
10. Federal Register: February 14, 2003, (Vol. 68, No. 31)[Page 7554-7558]. *Aspergillus flavus* AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
11. Federal Register. March 12, 2003. *Aspergillus flavus* AF36; Notice of receipt of an application to register a new active ingredient. (Vol. 68, No. 48)][Page 11841-11843]
12. Notice of availability: Registration of New Active Ingredient (to be published 2003).
13. Final Rule: Exemption from Tolerance (to be published 2003).

BPPD Data Evaluation Records/Reviews

Health Effects

Cindy Schaffer and Roy Sjoblad, USEPA, OPP/BPPD. April 23, 1996. Data Evaluation Record of MRID 43972403: Acute Oral Toxicity Study in Rats.

Michael T. Watson and John Kough, USEPA, OPP/BPPD. March 29, 1999. BPPD Review of MRID 44626101: Analysis of Samples.

Michael T. Watson and John Kough, USEPA, OPP/BPPD. May 14, 1999. BPPD Review of Supplementary Information Analysis of Samples.

Carl Etsitty and John Kough, USEPA, OPP. April 02, 2003a. BPPD Review of MRID 45739101: Dose for Acute Pulmonary study.

Carl Etsitty and John Kough, USEPA, OPP. April 02, 2003b. BPPD Review of MRID 45798101: Acute Pulmonary Study with Tween 80.

Carl Etsitty and John Kough, USEPA, OPP. April 02, 2003c. BPPD Review of MRID 45798201: Acute Pulmonary Study without Tween 80.

Carl Etsitty and John Kough, USEPA, OPP. April 02, 2003d. BPPD Review of MRID 45739104: Hypersensitivity incidents.

Ecological, Environmental Effects

Tomimatsu, G. S. and Robert H. Rose. USEPA, OPP. April 24, 1996. Memorandum to Shanaz Bacchus. BPPD Review of Information Submitted by USDA Southern Regional Research Center/IR-4 for an Experimental Use Permit for *Aspergillus flavus* AF36; Request for Waiver for Non-Target Plant Testing.

Gail Tomimatsu and Robert I. Rose. USEPA, OPP. April 24, 1996. BPPD review of MRID 43763403, 437634035, No MRID - Vol. 6: Information Submitted Southern Regional Research Center for NonTarget Plant testing. Request for waiver.

Doug Gurian-Sherman and Gail Tomimatsu, USEPA, OPP. June 23, 1999. BPPD Review, MRID 44464202: Review of Request for Waiver of Non-Target Organism Safety Effects Tests for EUP Renewal and Expansion for Biopesticide Containing *Aspergillus flavus* AF36 (AF36).

Doug Gurian-Sherman and Gail Tomimatsu, USEPA, OPP/BPPD. June 23, 1999a. BPPD Review, Additional Rationale for Data Waiver Request for Subdivision M Guidelines 154A-16, 17, 19, 20, 22, 23, 24. (No MRID).

Alan Reynolds, Gail Tomimatsu and Zigfridas Vaituzis. USEPA, OPP. April 29, 2003. BPPD Review of MRID 45798102: Honeybee study.

Tomimatsu, G.S. 2003. USEPA, OPP. April 22, 2003. BPPD Review of Amendment Number 1 to MRID 45307202: *Aspergillus flavus* isolate AF36: Non-target Organism and Environmental Safety Information.

Gail Tomimatsu and John Kough, USEPA, OPP/BPPD. May 15, 2003. BPPD Review of MRIDs 45307201, 45307202: Soil and Air Monitoring Studies and Product Performance Testing (Efficacy).

Gail S. Tomimatsu and Zigfridas Vaituzis, USEPA, OPP. May 15, 2003. BPPD Data Evaluation Record of MRID 45798102: Avian Inhalation Test, Tier I.

BPPD PRAT ACTION CODING FORM

EPA 71 (Rev. 10/1999)

REGISTRANT/COMPANY NAME:

Arizona Cotton Research + Protection Council

Fast Track: Yes ☐ No ☒

Reviewer Shan Bacchus

Assigned by J. Downing

EPA REG./FILE SYMBOL 71693-R

(Note: If Fast Track, you may need to change Reviewer's Name in PRAT.)

ACTION CODE 101

(New A.I./EUP'S/Tolerances: Yes ☒ No ☐)

DATE OF APPLICATION 5-23-03

EPA RECEIVED DATE 5-28-03

BPPD RECEIVED DATE 5-29-03

Comment Letter

SUBMISSION BARCODE ?

ASSIGNED IN PRAT: Yes ☐ No ☒

COMPLETED BY J. Downing DATE 5-29-03

LOGGED IN BRATS: Yes ☒ No ☐ DATE 5-29-03 COMPLETED BY J. Downing

RAL RECEIVED _____ DATE _____
(RAL initials)

FINAL ACTION

RESPONSE CODE: _____

RESPONSE DATE: _____

MOS: _____ (1) C/As All
_____ (2) Not Applicable
_____ (3) Selective

CRP	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Restricted Use	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Manufacturing Use	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Exclusive Use	Yes <input type="checkbox"/>	No <input type="checkbox"/>

BPPD PRAT ACTION CODING FORM

PM 90: Janet Anderson

REVIEWER: BACCHUS

(ASSIGNED BY: POH)

EPA REG./FILE SYMBOL 71693-R 865001

ACTION CODE 131

SUBMISSION BARCODE _____

Date on Application 12-10-98

EPA Received Date 12-11-98

PM Received Date 12-28-98

Assigned in PRAT YES _____ NO ✓ No DC Case

Completed by: S. Diana Hudson Date 1-8-99

FINAL ACTION

Response Code _____

Response Date: 1 / 1

MOS: _____ (1) Cite-All

_____ (4) Not Applicable

_____ (8) Selective

CRP: Yes _____ No _____

Restricted Use: Yes _____ No ✓

Manufacturing Use: Yes _____ No _____

Exclusive Use: Yes _____ No _____



FIEN - Jack Cooper -
Food Industry
Environmental
Network phone 301
384 8287 fax 301 384
8340 <JLC@fien.com>

06/16/03 05:10 AM

To: "Crop Protection, Agricultural Research and Food Safety Issues
Distribution Lists" <JLC@fien.com>
cc: Shanaz Bacchus/DC/USEPA/US@EPA
Subject: Aflatoxin Reduction Research in Peanuts - EPA Seeks Public
Comments by July 11 on a proposed experimental use permit
submitted by Circle One Global, Inc. of Shellman, Georgia for "... field
testing of a new end-use product of a microbial pesticide containing
the active ingredient, Aspergillus flavus NRRL 21882 ... Application of
the pesticide is proposed to reduce aflatoxin-producing colonies of
Aspergillus flavus on the crop and in the soil by competitive
displacement ..." ...

CROP PROTECTION, AGRICULTURAL RESEARCH AND FOOD SAFETY

* Aflatoxin Reduction Research in Peanuts - EPA Seeks Public Comments by
July 11 on a proposed experimental use permit submitted by Circle One
Global, Inc. of Shellman, Georgia for "... field testing of a new end-use
product of a microbial pesticide containing the active ingredient,
Aspergillus flavus NRRL 21882, in a non-crop destruct program. The product
is to be ground applied and is a granular formulation. At the proposed use
rate of 20 lbs/acre, the equivalent amount of active ingredient applied is
only 0.002 lbs/acre. The requested EUP is for a total of 5,000 acres to be
treated for a total application of 10 lbs of the active ingredient.

Concurrent with this application, the applicant filed a pesticide petition
... for a temporary exemption from tolerance for residues of Aspergillus
flavus NRRL 21882 in/on the food/feed commodity peanut. Application of the
pesticide is proposed to reduce aflatoxin-producing colonies of Aspergillus
flavus on the crop and in the soil by competitive displacement. Testing of
100 lbs of the active ingredient will occur in three States: Alabama,
Florida, and Georgia ..." - EPA OPPTS OPP Contact: Shanaz Bacchus,
Biopesticides and Pollution Prevention Division at 703 308 8097; e-mail:
<mailto:Bacchus.Shanaz@EPA.gov>Bacchus.Shanaz@EPA.gov - EPA June 11 Federal
Register:

<<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/03-14462.htm>
><http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/03-14462.htm>

The above information was sent to you by:

Jack L. Cooper
Food Industry Environmental Network (FIEN)
33 Falling Creek Court; Silver Spring, Maryland 20904
Phone: 301/384-8287 --- Fax: 301/384-8340
E-Mail: JLC@fien.com --- WWW: <http://www.fien.com>

FIEN is a regulatory and policy e-mail alert service for food
industry trade associations, consulting firms, professional
societies, educational institutions, government officials, and
others with an interest in the food and agricultural industries.

When information comes to FIEN's attention that is believed to
be of interest to those whose names are on one or more of the
FIEN Subject Matter Distribution Lists, the information is
summarized and distributed in as timely a manner as possible.

Typical areas of FIEN information distribution include:
biotechnology, crop protection, food safety, nutrition,
environmental protection, occupational safety and health,
risk assessment, bioterrorism and numerous related topics.

The individual FIEN distributions are collated each day into a
"FIEN Food Environmental Daily," and each week into a
"FIEN Food Environmental Weekly." These newsletters are
intended to be used as reference sources and backup, and as a
source of information on topics for which an individual has not
had their name placed on an individual subject matter distribution list.



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W. 7511C
Washington, D.C. 20460

EPA Reg.
Number:

71693-1

Date of
Issuance:

JUN 24 2003

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

under FIFRA, as amended:

Term of Issuance

Conditional

Name of Pesticide Product:

Aspergillus flavus AF36

Name and Address of Registrant (include ZIP Code):

Mr. Larry Antilla
Arizona Cotton Research and Protection Council
3721 East Wier Avenue
Phoenix, Arizona 85040-2933

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided that you do the following:

1. Change the label by revising the EPA Registration Number to read, "EPA Reg. No. 71693-1".
2. Submit five copies of the revised final printed label for the record.
3. The following data are required within 30 months of the conditional registration date:
 - (a) analyses of 5 production batches to include:
 - (i) certifications of limits;
 - (ii) identification of *A. flavus* AF36 by either DNA analysis or some other method different from the vegetative compatibility method now in use;
 - (iii) analysis and quantification of metabolites and other unintentional ingredients, including aflatoxin analysis by High Pressure Liquid Chromatography (HPLC) or Gas Chromatography (GC);
 - (iv) identification and enumeration of potential human pathogens;
 - (v) storage stability; and
 - (vi) viability data.
 - (b) efficacy data from large scale trials in Texas.

All batches containing human pathogen, metabolites and unintentional ingredients above regulatory levels must be destroyed.

SB:7511C:06232003:006456:716931

Signature of Approving Official

See next PAGE

Date

6/24/03

EPA Form 8570-2

CONCURRENCES

SYMBOL	7511 C							
SURNAME	BA... ..							
DATE	6/23/03							

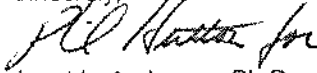
41

OFFICIAL FILE COPY

Any requests for time extensions to provide the data listed above must be submitted in writing prior to the appropriate deadline. If EPA determines, at any time, that additional data are required to maintain in effect an existing conditional registration, the Agency will require submission of such data under Section 3(c)(2)(B) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the approved label in connection with this conditional registration is enclosed for your records. If you have any other questions regarding this registration, do not hesitate to email Shanaz Bacchus at bacchus.shanaz@epa.gov or call her on 703-308-8097.

Sincerely,



Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution Prevention Division

cc: file 71693-R
Encl.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 20 2003

MEMORANDUM

SUBJECT: Consideration of a conditional registration of the active ingredient *Aspergillus flavus* AF36 (PC Code 006456, EPA Registration Number 71693-R) for use on cotton in Arizona and Texas, and an exemption from tolerance for cotton and its food/feed commodities associated with the use of this active ingredient (Pesticide Petition 8E5001).

----- **DECISION MEMORANDUM** -----

FROM: Janet L. Andersen, Director *Janet L. Andersen*
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs

TO: James Jones, Director
Office of Pesticide Programs

ISSUE

Should the Agency grant a conditional registration under FIFRA § 3(c)(7)(C) for the new microbial active ingredient, *Aspergillus flavus* strain AF36 (PC Code 006456, EPA Registration Number 71693-R) as an antifungal pesticide to reduce aflatoxin-producing colonies of *A. flavus* on cotton in Arizona and Texas?

Also, should the Agency grant an exemption from tolerance for residues of the active ingredient, *Aspergillus flavus* strain AF36, on cotton and its food/feed commodities as requested in Pesticide Petition 8E5001?

APPLICANT INFORMATION

The application for the use of this new active ingredient, *Aspergillus flavus* AF36, and the Pesticide Petition 8E5001 were filed by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390, on behalf of Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, Arizona 85040-2933.

BACKGROUND AND CONCLUSIONS

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed available and submitted data and information regarding the proposed use of *Aspergillus flavus* AF36, a non-aflatoxin-producing (atoxigenic) strain of *A. flavus*. Evaluations of the data and conclusions are summarized and discussed in the attached Biopesticide Registration Action Document (BRAD). *Aspergillus flavus* AF36 (also called AF36) is to be applied at less than 0.01 lb of the active ingredient per acre. The applicant proposes a single, seasonal, prebloom application to cotton fields in Arizona and Texas. AF36 apparently displaces aflatoxin-producing strains of *A. flavus* from cotton fields and cotton, with a potential concomitant reduction of aflatoxin, a public health hazard. There is no other pesticide registered for the reduction of aflatoxin-producing colonies of *A. flavus*. For these reasons, *Aspergillus flavus* AF36 qualifies for an automatic presumptive finding for a conditional registration, and its use is presumed to be in the public interest. Sufficient data are available to support granting a conditional registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

While there are data gaps, the available and submitted data, which have been reviewed, comply with the Food Quality Protection Act of 1996. The health effects database support an exemption from tolerance for residues of *Aspergillus flavus* strain AF36 in/on cotton and its food/feed commodities. No toxicity endpoints were identified to justify setting a numerical tolerance for *A. flavus* AF36. Cotton itself is not a dietary commodity and residues of AF36 are not likely to survive the processing of cottonseed into its oil or meal. Thus, secondary transfer of AF36 to meat and milk are not likely to occur. Even if there was any potential aflatoxin associated with the use of AF36, in/on cotton food/feed commodities, those levels must meet the aflatoxin standards regulated by the Food and Drug Administration. Dietary, non-occupational dermal and inhalation exposures, as well as cumulative and aggregate exposures and risks are not likely to be greater than those which currently exist to the naturally occurring *A. flavus* strains. Thus, minimal to non-existent risks via dietary or non-occupational dermal and inhalation exposures are expected.

The applicant requested that data be waived for acute dermal toxicity/pathogenicity, primary dermal irritation, primary eye irritation, intraperitoneal and immune response studies. BPPD accepted the rationales submitted by the applicant to waive these data requirements. The justifications included (a) the non-toxic, non-infective acute oral and pulmonary effects, (b) a low application rate, (c) minimal to no pesticide drift based on the granular nature of the pesticide, (d) the ubiquitous occurrence of *Aspergillus* fungi, and (e) exposures which are not likely to be above background levels.

BPPD has not identified any acute, subchronic, chronic, immune, endocrine or dietary exposure issues that might affect human adults, infants and children. Because there are no threshold effects of concern to human adults, infants and children, when AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. Thus, there is a reasonable certainty of no incremental adverse effects to human adults, infants and children, and to the environment from the use of this active ingredient. Potential occupational exposure is mitigated by use of appropriate Personal Protective Equipment as required by the Worker Protection Standards.

Submitted data indicate no potential incremental adverse effects to avian and honey bee

non-target organisms. Soil and air monitoring data demonstrate that application of AF36 does not increase the total *A. flavus* in treated areas. AF36 may incite significant changes in the incidence of the toxigenic *A. flavus* strains resident in the agroecosystem. Justifications in support of data waiver requests for avian oral, freshwater and marine vertebrates and invertebrates, non-target plants and other non-target organisms were acceptable. Based on submitted avian and mammalian studies, exposures of AF36 to endangered avian and mammalian species and to wildlife are not likely to pose any incremental adverse effects.

CONDITIONS OF REGISTRATION

The remaining data, analyses of 5 production batches, are due within 30 months of registration. These conditions include (a) certification of the nominal limits of the active ingredient, identification and quantification of microbial contaminants and unintentional ingredients, a confirmatory method to identify AF36, storage and viability data, from 5 production batches; and (b) efficacy trial in Texas. If the applicant wishes to register other uses, additional data will be required on a case by case basis.

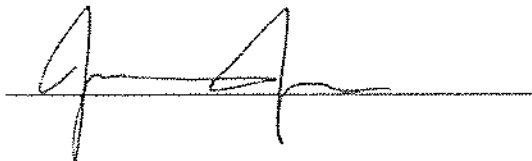
The applicant has committed to providing the data required to proceed to an unconditional Section 3(c)(5) registration. BPPD recommends in favor of a conditional registration and an exemption from tolerance on cotton food/feed commodities for the new microbial active ingredient, *Aspergillus flavus* strain AF36.

OFFICE DIRECTOR CONCURRENCE

Based on the discussion above and the summarized data evaluations in the attached BRAD, BPPD recommends that the microbial pesticide containing the new active ingredient *Aspergillus flavus* strain AF36 (PC Code 006456) be conditionally registered under 3(c)(7)(C) of FIFRA for use on cotton in Arizona and Texas.

BPPD also recommends that an exemption from tolerance for residues of *Aspergillus flavus* strain AF36 on cotton food/feed commodity be granted to the applicant, on the basis of the review of the health effects data, which comply with the requirements of the Food Quality Protection Act of 1996.

Concurrence: _____



Non Concurrence: _____

Date: _____

6/23/03

Aspergillus flavus AF36

FOR USE ONLY IN THE STATES OF ARIZONA AND TEXAS

For displacing aflatoxin producing fungi

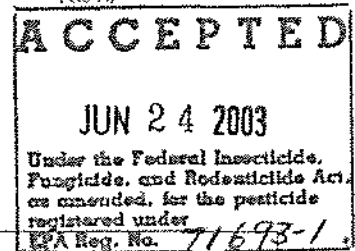
Aspergillus flavus AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied to cotton just prior to first bloom, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: *Aspergillus flavus* strain AF36* 0.0008%
Other ingredients: Wheat seeds (sterilized, catalogized)..... 99.9992%
Total: 100%

* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

CAUTION



First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693-1
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated cotton fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard.

Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to cotton to displace aflatoxin-producing strains of *Aspergillus flavus*.

Aspergillus flavus AF36 is a living fungus growing on sterile wheat seed, which serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur at irrigation), *Aspergillus flavus* AF36 will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi are spread.

Ground Application:

1. Apply *Aspergillus flavus* AF36 with a cultivator mounted granular applicator to the surface of the soil under the plant canopy. **DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.**
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to furrows.
3. *Aspergillus flavus* AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. Make a single application during the last cultivation before bloom.
4. Furrow irrigating the crop with at least 2 inches of water within three days after application of *Aspergillus flavus* AF36 will provide the best results.
5. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Apply by air at the same rate as for ground application. Cultivation after application may diminish efficacy.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers: Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



*Biopesticides and
Pollution Prevention
Division*

FAX

June 24, 2003

Pages: 5 (incl cover)

To: Dr. Mike Braverman
Interregional Research Project No. 4 (IR-4)
New Jersey Agricultural Experiment Station
Technology Center, 681 U.S. Highway 1 South
North Brunswick, NJ 08902-3390
732-932-9575 x 610 (phone) 732-932-8481 (fax)

From: Shanaz Bacchus, Chemist/Regulation Action Leader
US Environmental Protection Agency
Office of Pesticide Programs
Biopesticides & Pollution Prevention Division (7511C)
1200 Pennsylvania Ave NW, Washington, DC 20460
703-308-8097 (phone) 703-308-7026 (fax)

Message: *Aspergillus flavus* AF36 (EPA Reg. No. 71693-1)

Attached are the conditional registration notice and a stamped approved label for *Aspergillus flavus* AF36 for use on cotton in Arizona and Texas. The final rule for the exemption from temporary tolerance has been approved in connection with Pesticide Petition 8E5001 and will soon be published in the Federal Register.

If you have any questions, do not hesitate to call/email me.

Post-It® Fax Note	7671	Date	6/24/03	# of pages	5
To	Larry And. Ho	From	Shanaz Bacchus		
Co./Dept.	Ar. Cotton Dis. Ctr.	Co.	USEPA/OPP/PPD		
Phone #	602-428-0059	Phone #	703-308-8097		
Fax #	602-428-0407	Fax #	703-308-7026		

AF36/
Cotton/CA

4/4 w Phil

7/14/04

TX — similar to CA.

Cotton^{rowing} region — CA. What is? specify countries

Specify

AZ Cotton Council request for fee waivers ✓

AF36
Cotton
CA

IR-4 send petit. don't have to ask for fees.

or show microclimates similar

— full food exemption — no IV —

— efficacy pistachio

crop groups? — — — aflatoxin

background levels? — in toxicity

worker exposure?

bring in
IP

Dec 03

FDA

regulate

all

crops?

in place

those w/
susceptibility
to aflatoxin

a) Change BRAD (Living)

b) Label counties CA.

San Bernardino
Riverside
San Diego
Imperial

limited to Imp Valley

Set plug Phil

No

COTTON IN
CA NOTES

Teleconf w Mike

7/14/04

- a) Mike to get info on AF36 in CA (what counties).
- b) Imperial Valley.
may specify counties on label [Mike to send maps.]
- c) ~~more~~ to Need JIC, Tig - concursion CA reviews.
- d)

AF36
cotton
CA

PISTACHIO
NOTES

AT 36 mtg EU / pistachio 6/16/04

Now:

Now use Gauthier - or Nemphos mulling / phosmet
2-3 weeks before harvest -

- heat
- drying process -
- 98% pist sold as roasted nut - mitigates aflatoxin.

no reliable way to estimate pest pressure -

Now use JPM / Phoronone (1/2 ps mlt)
2" 100 mlt

Displ. aflatoxin
pop.

irrigation sprinkler ~ 90% acres

CPA - non regulated -
levels of toxicity / potential exposure

Processing issue -
mitigate -
new split hull's -
no storage problem.

3 samples ea 10 kg

Incl. large

2000A / CA.

1500 B / A → 3 m / lb.

Processing

Screening

Sampling for tissue analysis

150,000 ppb

10^6 ppb cotton seed

3×10^6 " "

Majority of pistachio growing areas

open / closed shell
internal defects.
adhering hull
dark shell →

aflatoxin → small nuts / dark skins

Pistachio

100,000 A - ⁷⁶1.5m ²⁰⁰⁴400 m/b ⁽¹⁾off yr bearing
₁₁₈ → 300

Damage Naval orange worm
birds
nice } precedes
aflatoxin
contamination

delay harvest → damage
died to 7 1/2% moisture — no build up ^{of fungus} after dry
early splits.

1/30,000 nut has high enough levels
nuts mature → capric acid → abortion of flowers.

flour tank — damaged nuts float

2.5 - 30% moisture → 7 1/2% H₂O (no more aflat. ^{contaminant})

1st week April ^{split} by mid May → Early ^{Apply} July infection)
Apply July prior to early split
Not at time of early split

aflatoxin of concern 30% → Europe — 2 ppb B₁
4 ppb Total

0.2 - 0.3 ppb for

15 ppb Total FDA aflatoxin

~~note~~ Affairs to get to nut must have split / cracked hull
Since 1/20,000 highest 150 ppb } 30% of samples -
500 ppb — contaminated

similar floater .
electronic eye sorter.

↓
stained,

↓
human eye

AZ, New Mexico TX Atch NV 99%CA

Temporary Tolerance

~~Wally Wally Wally~~

Meeting with Arizona Cotton Council and IR-4
June 16, 2004 in Room 912 A Crystal Mall 2
Crystal City, Arlington, VA

Proposed use of *Aspergillus flavus* AF36 on pistachios
3 yr Experimental Use Permit, CA

✓ Peter Cotty	pjcotty@srrc.ars.usda.gov>	
✓ Michailides, Themis J.	THEMIS@uckac.edu>	
✓ Larry Antilla	Lantilla@AZcotton.com	
✓ Dr. Robert Klein	hobk@pistachios.org	265
✓ Rebecca Sisco	rsisco@ucdavis.edu	
Michael Braverman	braverman@AESOP.Rutgers.edu	MB
✓ Gabrielle Ludwig	gludwig@slacconsult.com	
✓ Mark Doster		

USEPA/OPP/BPPD reps

✓ John Kough	kough.john@epa.gov	JK
✓ Carl Etsitty	etsitty.carl@epa.gov	CE
Gail Tomimatsu	tomimatsu.gail@epa.gov	gt
Dennis Szuhay	szuhay.dennis@epa.gov	DS
Shanaz Bacchus	bacchus.shanaz@epa.gov	B
✓ Hilary Hill	hill.hilary@epa.gov	HH
✓ Chris J. Pfeifer	pfeifer.chris@epa.gov	CP
✓ Annabel Fellman	fellman.annabel@epa.gov	AF
Rebecca Edelstein	edelstein.rebecca@epa.gov	



Michael Braverman
<braverman@AESOP.
Rutgers.edu>

06/11/04 08:58 AM

To: Peter Cotty <pcotty@src.ars.usda.gov>, "Michailides, Themis J." <THEMIS@uckac.edu>, Larry Antilla <LAntilla@AZcotton.com>, bobk@pistachios.org, Rebecca Sisco <rsisco@ucdavis.edu>
cc: Shanaz Bacchus/DC/USEPA/US@EPA, Dennis Szuhay/DC/USEPA/US@EPA
Subject: RE: reschedule June 16 from 2-4p.m./ AF36 pistachios-TELECONFERENCE NUMBER

All

For those of you that will be joining the AF36 pistachio meeting by phone, the number is [REDACTED]
The code is [REDACTED]

Attached is the agenda and a group of tables that Shanaz pulled out of the AF36 cotton Biopesticide Regulatory Action Document. It is a list of what we previously submitted for cotton and which will be discussed as citations for this registration. There are additional administrative volumes not listed that we will have to translate-bridge to pistachio. I think that constitutes the basis of the meeting discussion.

The Word file is the workplan section of the proposed EUP.

Looking forward to your participation.

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
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BIOPESTICIDES



MICROBIALS



· PHEROMONES



NATURAL PRODUCTS

-----Original Message-----

From: Michael Braverman [mailto:braverman@aesop.rutgers.edu]

Sent: Wednesday, June 09, 2004 1:54 PM

To: 'Michael Braverman'; Peter Cotty; 'Michailides, Themis J.'; Larry Antilla (LAntilla@AZcotton.com); 'bobk@pistachios.org'

Cc: Shanaz Bacchus (Bacchus.Shanaz@epamail.epa.gov)

Subject: RE: reschedule June 16 from 2-4p.m./ AF36 pistachios

All

Reminder-Our meeting with EPA to discuss AF36 on pistachio will be on June 16, 2-4 PM EST.

As I understand Larry Antilla, Peter Cotty, Themis Michailides, and Mark Doster will be joining by teleconference.

Bob Klein, Gabriele Ludwig and I will be there in person.

Shanaz- Could you let us know the procedure for the teleconference.

Thanks

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
<http://ir4.rutgers.edu/>

BIOPESTICIDES



MICROBIALS



PHEROMONES



NATURAL PRODUCTS

-----Original Message-----

From: Michael Braverman [mailto:braverman@aesop.rutgers.edu]

Sent: Friday, May 14, 2004 12:39 PM

To: Peter Cotty; 'Michailides, Themis J.'; Larry Antilla (LAntilla@AZcotton.com);
'bobk@pistachios.org'

Subject: FW: reschedule June 16 from 2-4p.m./ AF36 pistachios

All

Our meeting with EPA has been rescheduled for June 16, 2-4 PM. Please let me know if you will attend in person or by phone.

Thanks

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
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Agenda

Pre Registration Meeting for *Aspergillus flavus* AF36-Label Expansion to Pistachio

Biopesticides and Pollution Prevention Division, EPA-Crystal Mall 2

June 16, 2004

2-4 PM

- 1) Introduction - Dr. Bob Klein, California Pistachio Commission and Dr. Themis Michailides, and Dr. Mark Döster, University of California
- 2) Utilization of existing toxicology database
- 3) Utilization of existing Environmental effects, Non -Target Organism database
- 4) Experimental Use Permit

Agenda

Pre Registration Meeting for Aspergillus flavus AF36-Label Expansion to Pistachio

Biopesticides and Pollution Prevention Division, EPA-Crystal Mall 2

June 16, 2004

2-4 PM

- 1) Introduction - Dr. Bob Klein, California Pistachio Commission and Dr. Themis Michailides, and Dr. Mark Doster, University of California
- 2) Utilization of existing toxicology database
- 3) Utilization of existing Environmental effects, Non -Target Organism database
- 4) Experimental Use Permit

Notes for meeting with IR-4 on Wed., June 16, 2004 from 2-4 p.m. Room 912A-CM2

Tables taken from the *Aspergillus flavus* AF36 BRAD, which is online on our webpage.

Table 2a: Tier I - Acute Mammalian Toxicity of *Aspergillus flavus* AF36

Guideline	Study	Toxicity Category	Results	MRID #
152-10 *885.3050	Acute oral toxicity/pathogenicity	IV	Acceptable. LD ₅₀ > 5000 mg/kg. 5 male, 5 female Sprague Dawley treated 500 mg/ml or 6.3 x 10 ³ cfu/ml.	43972403
152-32 *885.3100	Acute inhalation	III	Pursuant to 40 CFR sec. 158.740(c), because the majority of the aerodynamic equivalent of the product is not composed of particles less than 10 microns in diameter, an inhalation study was not required. Nevertheless, this requirement was considered satisfied based on clearance observed in the acute pulmonary study.	45798201
152-32 *885.3150	Acute pulmonary toxicity/pathogenicity	N/A	Acceptable. AF36 not toxic, infective or pathogenic via intratracheal instillation to rats. Clearance by day 8.	45739101 45798101 45798201

Table 2b: Tier I - Data Waivers: Acute Mammalian Toxicity of *Aspergillus flavus* AF36

Guideline	Study	Toxicity Category	Comments	MRID No.
152-31 *885.3100	Acute dermal toxicity	N/A	Waived**	N/A
152-33 *885.3200	Intraperitoneal injection toxicity/pathogenicity	N/A	Waived** No toxicity observed during acute oral and acute pulmonary studies as discussed above.	43972403 45739101 45798101 45798201
152-35 *870.2400	Primary eye irritation	N/A	Waived**	N/A

Table 2b: Tier I - Data Waivers: Acute Mammalian Toxicity of <i>Aspergillus flavus</i> AF36				
Guideline	Study	Toxicity Category	Comments	MRID No.
152-34 *870.2500	Primary dermal irritation	N/A	<p>Waived** <i>Aspergillus</i> genus contains some known dermal sensitizers. Low exposure and application to commercial sites indicate minimal/negligible potential for non-occupational residential dermal exposure. In absence of data for AF36, label accordingly to mitigate occupational exposure. Low exposure and any potential pesticide drift can be mitigated with appropriate PPE.***</p>	N/A
152-36 *870.2600	Dermal sensitization			

Table 3a: Eco-Toxicology Summary/Studies Evaluated - <i>Aspergillus flavus</i> AF36			
Guideline No.	Study	Status, Classification & Comments	MRID Nos.
154-17 *885.4100	Avian injection	No incremental hazards of AF36 for avian species are anticipated for this use. Young bobwhite quail treated with <i>Aspergillus flavus</i> AF36 at a mean daily inhalation dose of 1.44×10^5 cfu per bird for five consecutive days exhibited no toxic or pathogenic effects during the 30 day observation period.	45798102 45307202
154-18 *885.4150	Wild mammal testing	No incremental hazards of AF36 for wild mammalian species are anticipated for this use. The mammalian acute oral pathogenicity and acute pulmonary toxicity tests (OPPTS 885.3050 and 885.3150), support this finding.	43763405 45307201 45307202 43972403
154-24 *885.4380 *850.3040	Honey bee testing, Tier I Field Testing of Pollinators	No incremental hazards of AF36 for honeybees are anticipated for this use. The exposure and potential hazard of <i>Aspergillus flavus</i> AF36 colonized-wheat seed to foraging honey bees (<i>Apis mellifera</i> L.) on blooming cotton was assessed for 30 days, following an aerial application at label rates. <i>Aspergillus flavus</i> AF36 applied once at 10 lbs/acre was not hazardous to honey bees.	45739102

Table 3b: Eco-Toxicology Summary: Data Waivers - <i>Aspergillus flavus</i> AF36			
Guideline No.	Study	Status, Classification & Comments	MRID Nos. Reviewed
154-16 *885.4050	Avian Oral Toxicity	No incremental hazards of AF36 for avian species are anticipated for this use. Results of soil and air population studies, the avian injection test (OPPTS 885.4100), and acceptable waiver rationale support this finding.	43763403 43763405 44464202 44452615 45739103 45307201 45307202 45798102
154-19 *885.4200	Fresh water fish testing	No incremental exposures of AF36 for freshwater aquatic invertebrates are anticipated for this use. Results of soil and air population studies for AF36 and <i>Aspergillus</i> and acceptable waiver rationale support this finding.	43763403 43763405 45307201 45307202 Rationale for waiver acceptable
154-20 *885.4240	Fresh water aquatic invertebrate testing		
154-20 *885.4280	Estuarine and marine animal testing		
154-22 *885.4300	Non-target plant studies, Tier 1	<i>A. flavus</i> strains are naturally abundant in plant debris and soil. No significant exposure above background levels expected.	Rationale for waiver acceptable.
154-23 *885.4340	Non-target insect studies	No incremental exposures of AF36 for insects are anticipated for this use. Results of soil and air population studies for AF36 and <i>Aspergillus</i> , honeybee field tests (OPPTS 885.4380 and 850.3040) and acceptable waiver rationale support this finding.	43763403 43763405

**EUP APPLICATION FOR AF36 ON PISTACHIOS
FOR 2005, 2006, and 2007**

April 22, 2004

G. Proposed Experimental Plan for:

**Displacement of *Aspergillus flavus* in pistachio orchards using the atoxigenic
Aspergillus flavus strain AF36**

(1a) Applicants:

Larry C. Antilla, Arizona Cotton Research & production Council, 3721 E. Wier Ave.,
Phoenix, AZ 85040.

Tel.: 602-438-0059; fax: 602-438-0407; e-mail: lantilla@azcotton.com

Dr. Robert Klein, Research Director, California Pistachio Commission, 1318 East Shaw
Ave., Suite 420, Fresno, CA 93710-7912.

Tel.: 559-221-8294; fax: 559-221-8044; e-mail: bobK@pistachios.org

(1b) Supervision of the experimental work:

Themis J. Michailides, Plant Pathologist, Department of Plant Pathology, University of
California, Kearney Agricultural Center, 9240 South Riverbend Ave., Parlier Ca 93648.

Tel: 559-646-6546; fax: 559-646-6593; themis@uckac.edu

Dr. Peter Cotty, Research Plant Pathologist, USDA/ARS, Div. of Plant Pathology and
Microbiology, Department of Plant Sciences, University of Arizona, Forbes 204, 1140
East Campus Drive, Tucson, AZ 85721

Tel: 520-626-5049; fax: 520-626-5704; pjcotty@srcc.ars.usda.gov

(2) State in which AF36 will be used: California:

Year	County	Area to be treated (acres)	Total acreage treated per year
2005	Merced	750	
2005	Madera	750	
2005	Kern	500	
2005			2,000
2006	Merced	750	
2006	Madera	750	
2006	Kern	500	
2006			2,000
2007	Merced	750	

2007	Madera	750	
2007	Kern	500	
2007			2,000

Aspergillus flavus AF36 will be applied at the rate of 10 lb per acre at one time during each production season as described in the following table.

Year	County	Area to be treated (acres)	Total product to be applied	Total acreage treated per year	Total Mat shipped to
2005	Merced	750	7500 lb		
	Madera	750	7500 lb		
	Kern/Tulare	500	5000 lb		
				2,000 in 2005	20,000 lb
2006	Merced	750	7500 lb		
	Madera	750	7500 lb		
	Kern/Tulare	500	5000 lb		
				2,000 in 2006	20,000 lb
2007	Merced	750	7500 lb		
	Madera	750	7500 lb		
	Kern/Tulare	500	5000 lb		
				2,000 in 2007	20,000 lb

(3) – **General background information:** Aflatoxins are a group of closely related toxins produced by certain molds (*Aspergillus flavus* and *Aspergillus parasiticus*) while these molds grow in various crops. Aflatoxins are potent liver carcinogens and are widely regulated by governments who have set very low tolerances for aflatoxins in food and feed. The aflatoxin-producing fungi, *A. flavus* and *A. parasiticus*, are widespread and probably occur in every pistachio (*Pistacia vera*) orchard in California. The major source of aflatoxin contamination in pistachio nuts is the "early split" nut, which is an abnormal pistachio nut that has both hull and shell split, exposing the kernel to decay by aflatoxin-producing fungi. *Aspergillus flavus* and *A. parasiticus* were found to decay 0.7% and 0.1% of the early split nuts in commercial pistachio orchards (Doster & Michailides, 1994. Phytopathology 84:583-590). The pistachio growers and processors in California have shown concern about the aflatoxin producing *Aspergillus flavus* and *A. parasiticus* and would like to have methods to **displace them or reduce them in the soil of pistachio orchards.**

Not all strains of *A. flavus* are capable of producing aflatoxins. In a study of isolates from California pistachio orchards, only 43% of the *A. flavus* isolates produced aflatoxins, whereas 100% of the *A. parasiticus* isolates produced aflatoxins (Doster & Michailides, 1994. Plant Dis. 78:393-397). Naturally occurring non-aflatoxin-producing ("atoxicogenic") strains of *A. flavus* have been used successfully to substantially displace toxigenic isolates of *A. flavus* in cottonseed and corn, and similarly, atoxicogenic strains of *A. flavus* have been used successfully to **displace toxigenic *A. parasiticus*** in peanuts.

The most successful use of atoxicogenic strains to **displace toxigenic *A. flavus*** is the use of the atoxicogenic strain AF36 in cotton fields in Arizona and Texas. In 2003 the U.S. Environmental Protection Agency registered AF36 for use in commercial cotton fields in Arizona and Texas. For several years previously, AF36 had been used successfully in trials in commercial cotton fields

under an Experimental Use Permit. The atoxigenic strain AF36 is grown on wheat, which is then applied in the cotton field prior to bloom. In 2001 an *A. flavus* isolate from California was identified as belonging to the atoxigenic strain AF36, demonstrating that AF36 occurs naturally in California. Furthermore, AF36 has been found to be naturally occurring throughout the pistachio growing regions of California and to make up approximately 6% of the *A. flavus* isolates naturally occurring in commercial pistachio orchards. In 2002 and 2003, we performed preliminary experiments with AF36 in a research pistachio orchard at the Keamey Agricultural Center in Parlier, California. The results of these experiments demonstrated that AF36 might be effective in displacing *A. flavus* in the soil of orchards and thus reducing contamination of pistachio nuts with aflatoxin in California.

The objective of this application is to determine the efficacy of the atoxigenic strain AF36 to displace aflatoxin-producing fungi in commercial pistachio orchards under commercial cultural practices. Because aflatoxin-producing strains of *A. flavus* and *A. parasiticus* colonize pistachio litter on the orchard floor (besides decaying pistachio nuts) (Doster & Michailides, 1994, Plant Dis. 78:393-397), AF36 might also function by displacing aflatoxin-producing fungi in plant litter. As much as possible, the application of AF36 in pistachio orchards will follow the methods used in cotton fields in Arizona and Texas. For example, the same rate of application (10 lbs product/acre) will be used and this AF36 will be applied mainly on the areas wetted by irrigation.

- **Target organisms:** Aflatoxin producing fungi (*Aspergillus* spp.) in soil of pistachio orchards.
- **Crop:** Pistachio (*Pistacia vera* L.). Pistachio is considered a relatively new crop in California grown in about 90,000 acres (California Pistachio Industry Statistics, Annual Report, Crop Year 2003-2004). Typical yields range from less than 2,000 lbs in an off year in particular areas to over 4,000 lbs in an on year. An average of about 3,000 lbs per acre is common for Kern County, but an average of 2,500 lbs per acre is for Madera/Merced counties. The majority of the product is used as a snack food. In essence though, all produced product (nuts) can be marketable at some price. For instance, an average return per pound (taking into account all the different quality parameters) was \$1.11 in 2002.
- **Major geographic areas where AF36 will be used:** Merced, Madera, and Kern Counties in California.
- * - **Desired month of application:** July.
- **Treatments:**
Treatment #1. Untreated (control).
Treatment #2. Wheat colonized by AF36 identical to that registered for use on cotton.
Rate: 10 lbs product/acre applied to the orchard floor. Application timing: a single application in late spring or early summer (July) prior to irrigation.
- **Use pattern:** Once per year
- **Plot size:**
In Merced County, 1,500 acres (750 acres treated and 750 acres not treated – control);
In Madera County, 1,500 acres (750 acres treated and 750 acres not treated – control);
In Kern/Tulare Counties, 1,000 acres (500 acres treated and 500 acres not treated – control).
- **Number of plots:** 6 plots total with each pair of plots (treated and untreated) serving as a replication, thus a total of three replicates. Comparisons will be made with both Analysis

of Variance and repeated measures statistics. For repeated measures statistics, 6 to 12 locations in each plot will be sampled repeatedly during the experimental period.

Details on the proposed experimental program:

The experimental design will be randomized block with three replications. For each block of 500-750 acres treated with AF36, a nearby similar 500-750 acres block of commercial orchards will be selected for the untreated (control) comparison. Thus a total of 500 acres in Kern County, 750 acres in Merced County, and 750 acres of pistachios in Madera County will be treated with AF36. The sizes of each treated and untreated area needs to be relatively large due to neighboring field influences and movement of the fungi from outside of treatment areas as previously demonstrated for cotton in Arizona and Texas. Large plots are also needed to allow for accurate estimation of the movement of AF36 into the canopy of pistachio trees from the ground (where it will be applied); see supporting preliminary data in Appendix 4.

The randomized block design experiment will have three replications represented by the blocks of pistachio orchards in Merced, Madera, and Kern Counties. In each county, 500-750 acres will be treated with AF36, while one nearby 500-750 acre block of orchards, respectively, will not be treated with AF36 (controls). The repeated measures design will have 6 to 12 replicates.

(4) Objectives of the proposed project:

1. Displace toxigenic *Aspergillus flavus* populations with atoxigenic *A. flavus* (strain AF36) in pistachio orchards in California.
2. Monitor spread and survival of AF36 *A. flavus* in pistachio orchard in California.
3. Perform dissipation study to assess *A. flavus* in general and *Aspergillus flavus* AF36 in specific on pistachios from harvest to end use.

- Data collection

Multiple samples of soil, plant debris on the orchard floor (such as male inflorescences), leaves, and nuts from each treated and nontreated blocks in each county will be collected. The density and strain of *A. flavus*/*A. parasiticus* in soil and leaf samples will be determined. The plant debris and nuts will be examined for colonization by *A. flavus*/*A. parasiticus*, and the strain of observed fungi will be determined. Soil samples will be collected prior to applying the wheat (June) each year and also during the harvest period. Both qualitative and quantitative comparisons will be made after one year to assess influences on the overall *A. flavus* communities. All other samples will be collected during the harvest period (September-October).

We plan to use the AF36 for 3 consecutive years (2005, 2006, and 2007) for collecting the data in support of the registration of this use. Soil samples will also be collected one year after the final application to quantify long-term and cumulative influences of applications.

A dissipation study will be initiated in the first year of this experiment. Samples of fruit will be collected from treated and non treated areas and will be followed in the processing pistachio plant to determine any survival of *A. flavus*. It is expected that processing will substantially reduce the level of AF36 on the nuts. All pistachio nuts are dried using heat during processing, although the details of the drying vary for the

different processing plants. Typically, high heat (120° to 180° F) is applied for several (4 to 6) hours followed by lower heat until the nuts are dry enough to be stored. Additional drying may be done in silo with fan-forced ambient air with some heating to about 100° F at night. One study found that drying pistachio nuts substantially reduced fungi on the nuts, from greater than 10,000 propagules per gram to less than 1,000 per gram (King and Goodman, 1993). In addition, the pistachio nuts are frequently fumigated with phosphine to control insects, which has been found to also control *A. flavus* on peanuts (Castro et al., 1996). Finally, roasting pistachio nuts at high heat 265° F for 3 to 4 hours should also be effective in eliminating any fungus before it reaches the consumer.

To determine any survival of *A. flavus* AF36 in nuts after processing, replicated samples will be collected from each of the treated and nontreated orchards. Each sample of each category will be split into two subsamples. One subsample will be used to determine colony forming units (CFU) of AF36/g nut after harvesting and before processing, and the second subsample for determining CFU of AF36/g nut after processing. The nuts will be hulled using our experimental huller and dried at temperatures and conditions used commercially as described above. Part of the dried nuts of each sample will be used to determine CFU of AF36/g nuts after drying (raw nuts). And the rest will be roasted at temperatures and conditions used commercially as described above. Then a final CFU of AF36/g nut will be measured to determine if any AF36 propagules survived (roasted nuts). Based on the temperature requirements for growth and survival of *A. flavus*, it is expected that no propagules of AF36 will survive the drying and roasting processes of pistachios.

(5) Quantity of the AF36 requested for use:

As outlined in the table above, 20,000 lbs AF36 product will be required for the experimental plan. The material will be manufactured at the Arizona Cotton Research and Protection Council/USDA Agricultural Research Service collaborative atoxigenic strain manufacturing facility. Since we are planning to treat 2,000 acres at a rate of 10 lbs per acre (the rate also used in commercial cotton fields in Arizona), the total amount of the registered and use product requested is 20,000 lbs per year. Thus for all three years of the experimental program 60,000 lbs of colonized wheat will be required. The 60,000 pounds of end use product relates to approximately 0.5 pounds of active ingredient.

(6) Propose a suitable duration and justification for the permit commensurate with the program.

For atoxigenic strain technology to be viable and to reach it's maximum utility, long-term and area-wide influences of atoxigenic strain treatments are needed. In order to assess long-term and area-wide effects relatively large areas must be treated over multiple years. The proposed acreage 500 to 1000 acres is what we consider to be the minimum needed to assess area-wide effects based on experience with using AF36 in cotton production in Arizona. To assess multi-year and cumulative influences, three years of treatments is a minimal required. Furthermore, because we are dealing with determination of fungal propagules in soil and there are a lot of factors that can affect the soil microbiology before and after the application of AF36, we would expect large variations between the treatments and among replicates in each County. Therefore, we will need data from at least three years in order to normalize such variations and also to obtain meaningful results on the displacement of the toxigenic *A. flavus* population in pistachio orchards with the atoxigenic AF36. Other reasons for a 3 year plan include the on year/off year production cycle (pistachio is considered an alternate crop), weather differences from year to

year, and navel orangeworm (NOW) infestation of the crop. NOW infestation of the crop predisposes pistachio to infection by *A. flavus*. In addition, the levels of *A. flavus* and/or *A. parasiticus* are much lower in California pistachio orchard soils than in those of soils in Arizona cotton fields, and one would expect that determining displacement of toxigenic *A. flavus* strains by the atoxigenic *A. flavus* Af36 in California orchards may be more difficult than in Arizona cotton fields.

(7) State the method of disposition of any unused material left at the conclusion of the testing program.

No material will be left over. Exactly the amount to be applied to orchards will be shipped to California. Incidental leftover material, if inadvertently generated, will be autoclaved and applied in our Center's compost area since this material will be sterilized (autoclaved) wheat seed.

Addendum

Describe your test facilities where these studies will be conducted:

The actual AF36 application will be performed in commercial pistachio orchards in Merced, Madera, and Kern Counties in California. Processing of samples will be done in the plant pathology laboratories at the Kearney Agricultural Center, where all necessary equipment (such as microscopes, incubators, autoclave, and flow hoods) is already present. Determination of the AF36 strain will be done using tester strains available in our laboratory using the vegetative compatibility grouping (VCG) test.

Appendix 4. Supporting preliminary data

We have been performing preliminary experiments investigating the use of atoxigenic strains of *A. flavus* in research pistachio orchards at the Kearney Agricultural Center since 2001. In cooperation with Dr. P. Cotty of ARS/USDA, two atoxigenic isolates (A564 and A815) were selected in 2001 (from over 600 isolates of *A. flavus* strain L from California orchards) for application in a research pistachio orchard. The atoxigenic strains were grown on wheat, which was then applied to the orchard floor in early summer (10 lbs/acre). After irrigating the orchard, sporulation of *A. flavus* was observed on the wheat in the orchard and continued to be observed throughout the summer. In the areas where the wheat was applied, the applied atoxigenic strain became the dominant strain in the soil (when samples were collected approximately 3 months after applying the wheat) (Table 1). Although the aflatoxin-producing species *A. parasiticus* was very common in the soil before applying the wheat, *A. parasiticus* was only present at very low levels in the soil three months after applying the atoxigenic strains (Fig. 1A).

In 2001 an *A. flavus* isolate from California was identified as belonging to the atoxigenic strain AF36, which is being used currently in commercial cotton fields in Arizona to substantially reduce the aflatoxin contamination of the cottonseed. Because AF36 has been so successful in Arizona, this strain was included in the orchard experiment in 2002 (along with the two atoxigenic strains used in 2001). On 1 July, wheat seeds infected with these strains were applied at the rate equivalent to 10 lbs/acre in a research pistachio orchard. Almost all of the *A. flavus* isolates from the soil in the treated areas belonged to the applied atoxigenic strain (93.3 to 98.3% of the isolates, depending on strain) (Table 2). All three strains were detected in the untreated area, indicating some movement of the atoxigenic strains. The density of *A. flavus* on leaves did not differ between treatments (Fig. 2B). The atoxigenic strains were detected on the leaves, ranging from 42.4 to 62.8% of the isolates (depending on treatment) (Table 3), which indicates good movement of the atoxigenic strains up into the canopy of the tree. In 2003 the atoxigenic strains were not applied in this orchard, but soil samples were collected on 19 August to determine the persistence of the atoxigenic strains. These samples are still being evaluated. The density of *A. flavus*/*A. parasiticus* in the soil and on the leaves increased over the time period of this experiment (Figure 2). The level of the aflatoxin-producing species *A. parasiticus* in the soil remained low in areas that had been treated with an atoxigenic strain (Figure 1).

In 2003 we initiated a biocontrol experiment in a research pistachio orchard that was irrigated by microsprinklers. On 1 July, wheat seeds infected with the atoxigenic strain AF36 were applied. On 23 September, leaf and additional soil samples were taken and are still being evaluated. Also, early split nuts were collected and found to have very low incidences of decay by *A. flavus* (0.0 and 0.5% of the early split nuts for nontreated areas and areas treated with AF36, respectively) (Table 4), indicating that applying AF36 to the soil does not increase the levels of decay in the nuts.

Atoxigenic strains of *A. flavus* occur naturally in commercial pistachio orchards in California. Isolates of *A. flavus* from commercial pistachio orchards were evaluated, and all three atoxigenic strains AF36 (6.3% of the 430 isolates evaluated), A564 (2.1%), and A815 (1.9%) were detected (Table 5). Furthermore, the atoxigenic strain AF36 has been found in commercial pistachio orchards in Fresno, Kern, Kings, Madera, and Tulare Counties in California, so this strain occurs throughout the major pistachio growing region.

Table 1. Incidence of atoxigenic strains of *Aspergillus flavus* in the soil in a research pistachio orchard in 2001.

Treatment	Percentage of isolates belonging to specified strain			
	Prior to applying wheat		Three months after applying wheat	
	A564	A815	A564	A815
Wheat with A564	0.0 ns	0.0 ns	93.8 a	0.6 c
Wheat with A815	0.0	0.0	0.0 b	98.9 a
Untreated control	0.0	0.0	1.3 b	33.3 b

Table 2. Incidence of atoxigenic strains of *Aspergillus flavus* in the soil in a research pistachio orchard in 2002. The atoxigenic strains A564 and A815 had been also applied in 2001.

Treatment	Percentage of isolates belonging to specified strain					
	Prior to applying wheat			Three months after applying wheat		
	AF36	A564	A815	AF36	A564	A815
Wheat with AF36	1.9 ns	10.7 b	26.7 b	95.0 a	0.0 b	1.7 b
Wheat with A564	0.0	91.7 a	0.0 b	3.3 c	93.3 a	3.3 b
Wheat with A815	0.0	0.0 b	100.0 a	1.7 c	0.0 b	98.3 a
Untreated control	0.0	8.6 b	26.7 b	49.1 b	7.1 b	15.0 b

Table 3. Incidence of atoxigenic strains of *Aspergillus flavus* on leaves three months after applying wheat in 2002.

Treatment	Percentage of isolates belonging to specified strain			
	AF36	A564	A815	Any applied strain
Wheat with AF36	37.8 ns	4.4 ns	20.6 ns	62.8 ns
Wheat with A564	0.0	28.9	22.2	51.1
Wheat with A815	7.5	5.4	46.3	59.2
Untreated control	25.4	3.8	13.2	42.4

Table 4. Incidence of kernels decayed by *Aspergillus flavus* and *Aspergillus niger* for early split nuts collected on 23 September, 2003. Colonized wheat was applied in the orchard on 1 July.

Treatment	Percentage colonized by specified fungus	
	<i>A. flavus</i>	<i>A. niger</i>
Wheat with AF36	0.5 ns	6.2 ns
Untreated control	0.0	5.3

Table 5. The natural occurrence of atoxigenic strains of *Aspergillus flavus* (from soil, fruit, and leaves) in commercial pistachio orchards and commercial fig orchards in California.

Strain	Percentage of <i>A. flavus</i> isolates belonging to specified strain	
	From commercial pistachio orchards ^a	From commercial fig orchards ^b
AF36	6.3	6.2
A564	2.1	1.0
A815	1.9	0.0

^a Out of 430 isolates of *A. flavus* obtained from commercial pistachio orchards.

^b Out of 97 isolates of *A. flavus* obtained from commercial fig orchards.

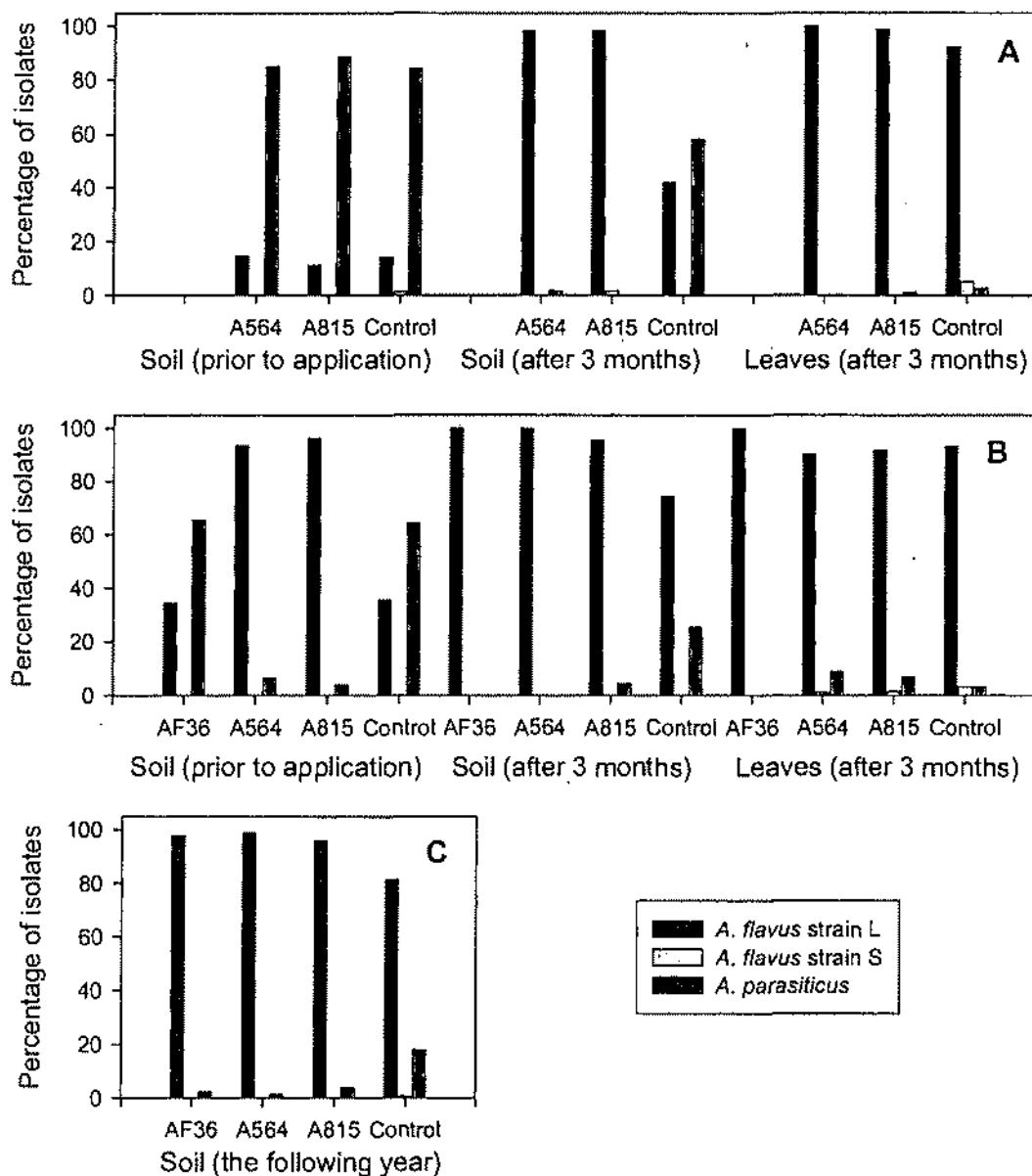


Figure 1. Percentage of isolates that belong to *Aspergillus flavus* or *A. parasiticus* for isolates obtained from soil or leaves collected from areas treated with atoxigenic strains of *A. flavus* (AF36, A564, or A815) or untreated areas. **A.** Samples collected in 2001. **B.** Samples collected in 2002. **C.** Samples collected in 2003.

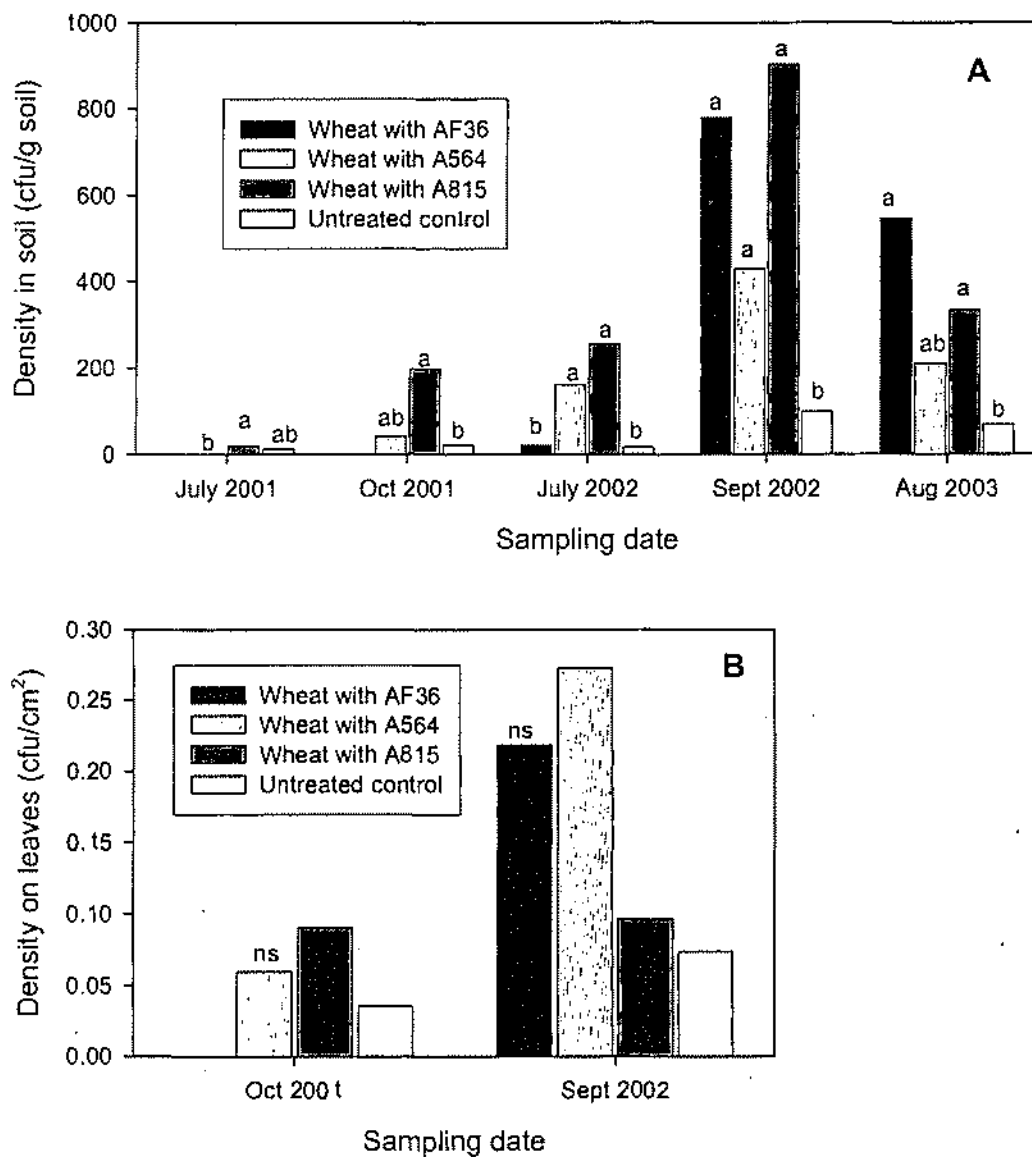


Figure 2. Density of *Aspergillus flavus*/*A. parasiticus* in soil or on leaves that were collected from areas treated with atoxigenic strains (AF36, A564, or A815) or untreated areas for various sampling dates. **A.** In soil. **B.** On leaves. Wheat infected with atoxigenic strains was applied in July 2001 and July 2002 (after collecting samples). AF36 was only applied in July 2002.

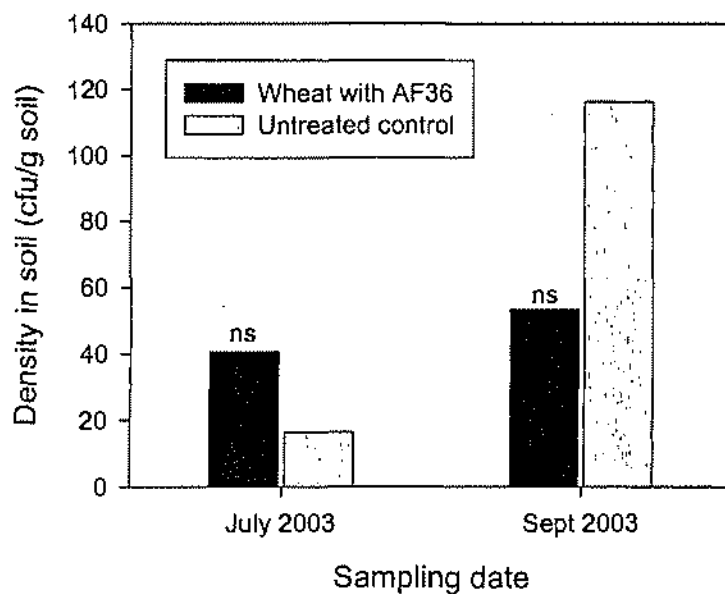


Figure 3. Density of *Aspergillus flavus*/*A. parasiticus* in soil from areas treated with AF36 and untreated areas in a microsprinkler-irrigated pistachio orchard prior to applying AF36 (July 2003) and almost 3 months after applying AF36 (September 2003).

Appendix 5. Attach resumé for Principal Investigators and Co-PI's

Dr. Michailides and Dr. Doster are plant pathologists with the Department of Plant Pathology, University of California, Davis, located at the Kearney Agricultural Center, Parlier. They have performed research on aflatoxin contamination of pistachio nuts in California orchards since 1990. Together with others, they have published more than 10 articles on aflatoxin research in peer-reviewed journals and numerous articles in magazines for growers. A list of their accomplishments include the following: identified special characteristics of pistachio nuts most likely to be contaminated with aflatoxin, which agricultural engineers have used to develop color sorters that are being implemented in processing plants; determined (in cooperation with Dr. Goldhamer) that mid May stress of pistachio trees increases the incidence of early split nuts (the main source of aflatoxin-contaminated nuts) at harvest; discovered that rootstock type and chemicals that break bud dormancy both affect the incidence of early split nuts; observed that early split pistachio nuts support an extra generation of navel orangeworm; and quantified the extent that delaying harvest increases both mold and navel orangeworm infestation of nuts. In addition, they discovered (with Dr. Goldhamer) for the first time on a tree crop that irrigation reduced aflatoxin contamination in figs; identified the special characteristics of aflatoxin-contaminated figs that could help the California Fig Industry to remove contaminated figs; determined (in cooperation with J. Doyle, a fig breeder) which new fig selections (with small ostioles) will most likely lead to lower aflatoxin contamination than the very susceptible currently grown Calimyrna cultivar.

In a recent project, Michailides and Doster are using Geostatistics and GIS technology along with aflatoxin analyses of 400 to 500 pistachio samples yearly. The goal of this project is to determine pistachio growing areas prone (hot") to aflatoxin contamination. Upon registration of the AF36, these "aflatoxin hot" pistachio orchards will be treated first.

Dr. Cotty is a Research Plant Pathologist and Lead Scientist with the Agricultural Research Service of USDA based at the University of Arizona in Tucson. Dr. Cotty is internationally recognized for his insights into the population biology and physiology of aflatoxin producing fungi and for contributions to the management of aflatoxin contamination. Dr. Cotty has performed research on aflatoxin producing fungi and aflatoxin contamination since 1986. Throughout this period his work has included field experiments on the control and epidemiology of aflatoxin contamination. This investigator's work has also included studies on the physiology, ecology, pathology, evolution, and genetics of aflatoxin producing fungi. He has been recognized by the USDA Secretary's Award for Personal and Profession Excellence, the ARS Technology Transfer Award, and twice by the Southern Regional Research Center with it's Outstanding Scientist Award. He also received the Arizona Farm Bureau Federation award for Environmental Technology in 2003. Dr. Cotty has authored or co-authored over 100 proceedings, extension articles, book chapters, patents and journal articles including 63 refereed research articles. He has also presented over 100 invited seminars at universities, regional, national, and international meetings.

We are available on June 14, 16, 17, 18, 21(AM only),
24 or 25th

At this point I am not sure how many of us will be
coming in person versus
teleconference.

Please let us know which date works best for BPPD.

Thanks

Michael Braverman, Ph.D.
Manager, Biopesticide Program
IR-4 Project, Rutgers University
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Phone 732-932-9575 ext 610
FAX 732-932-8481
<http://ir4.rutgers.edu/>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Tuesday, May 04, 2004 3:37 PM

To: Michael Braverman

Cc: 'Bob Klein'; Dennis Szuhay; Bob Holm; Jerry Baron
(Baron, Jerry); Dan

Kunkel (Kunkel, Dan); lantilla@azcotton.com; 'Doster,
Mark A.'; 'Peter

Cotty'; 'Michailides, Themis J.'

Subject: reschedule for 3rd week June/ AF36 pistachios?

I jumped the gun regarding this meeting and found that
some key players
cannot attend. Can we reschedule for the 3rd week of
June? A complete
package, which passes the screen and PR86-5 will have
to be here on September 1, in order for you to get a
decision for May 2005.

My apologies for not looking more closely at the
invitee list.

BIOPESTICIDES



MICROBIALS



PHEROMONES



NATURAL PRODUCTS

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Friday, May 14, 2004 10:03 AM

To: Michael Braverman

Subject: RE: reschedule June 16 from 2-4p.m./ AF36 pistachios

Your meeting has been rescheduled for June 16 from 2-4p.m. I tried to respond to all with history and don't know if it worked that way. Please inform your people and send an agenda about 2 weeks before the meeting.

Looking forward to meeting with you.

Sincerely,

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Michael Braverman <braverman@AESOP.Rutgers.edu>

05/12/2004 08:45 AM AST

To: Shanaz Bacchus/DC/USEPA/US@EPA



cc: 'Bob Klein' <bobk@pistachios.org>, Dennis Szuhay/DC/USEPA/US@EPA, "Dan Kunkel (Kunkel, Dan)" <kunkel@AESOP.Rutgers.edu>, Iantilla@azcotton.com, "Doster, Mark A." <MARK@uckac.edu>, 'Peter Colty' <pcotty@srre.ars.usda.gov>, "Michailides, Themis J." <THEMIS@uckac.edu>


bcc:

Subject: RE: reschedule for 3rd week June/ AF36 pistachios?

Shanaz

Sincerely,
Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097

Fax:  703-308-7026  AF36pistachioagenda.wp tables af36 cotton.wpc

 Pistachio EUP 04 April 22.c

Aspergillus flavus AF36 (ai # 006456)

Summary of studies submitted and DERs

December 5, 2002

Gdln #	MRID #	Study	DER	Toxicity Category	Action required
151A-10	437634-01?	Product Id. Published lit. Complete taxonomic description (colony morphology, photomicrographs) provided (The Genera of Hyphomycetes from soil (p.94) and Differentiation of <i>A. flavus</i> from <i>A. parasiticus</i> (M.A. Klitch and J.J. Pitt. Trans. Br. Mycol. Soc. 91 (1) 99-108 (1988).	C. Schaffer 2/20/96	na	
		Isolated from cottonseed, Yuma desert, AZ.			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Gdln #		MRID #	Study	DER	Toxicity Category	Action required
151A-11		437634-01	Manufacturing process. Sterilized wheat seeds inoculated with conidial suspension as per manufacturing SOP, then dried and transferred into storage bags until ready for use.	C. Schaffer 2/20/96		Supplemental
		445970-01	Liquid fermentation, incubation, followed by growth on wheat seeds, which is packaged into bags for use.	M. Watson 03/29/99		
		447137-01	Closed system used limits exposure, thus eliminating contamination. End-use product will contain at least 2.5×10^9 AF36 spores/gm.	M. Watson 03/29/99		

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Gdln #	MRID #	Study	DER	Toxicity Category	Action required
151A-13	437634-02	Analysis of Samples. Spore yield analyzed for yield based on turbidity studies.	C. Schaffer 2/20/96		Need more information on quality control (presence of microbial contaminants, mammalian pathogens, absence of aflatoxins and definitive fungal strain id)
	446261-01	Vegetative compatibility Coliforms: <2 of 50 seeds contaminated Bacteria: <6 of 50 seeds contaminated AF36 Spore count: >2.5 x 10 ⁹ /gm at 31°C and 100% relative humidity. Unlikely that contaminants or unintentional ingredients will be present at significant levels in the final product.	M. Watson 3/29/99		Supplementary. Can be upgraded to acceptable with clarification & description of use of tlc (Appears that vegetative compatibility does not quantify aflatoxin, but is qualitative method to isolate AF36)
	Response by P. Cotty	1. Aflatoxin standards = B ₁ , G ₁ , B ₂ , G ₂ , UV vis and quantifiable via scanning fluorescence densitometry (LOD 1 ppb) 2. Spores quantified by turbidimetry. Standard curve relates turbidity of spore suspension to viability (cfu)	M. Watson 5/14/99		Supplementary information acceptable for EUP. Need to find another detection technique to supplement vegetative compatibility detection. Should report spore viability.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SYMBOL	GdIn #	MRID #	Study	DER	Toxicity Category	Action required
151A-15			Certification of Ingredient Limits (see 151A-13). Potency of 100% <i>A. flavus</i> AF36 on 36 colonized seeds = 72.5 x 10 ⁹ spores/gm as ai. End-use product is capable of producing 2.5 x 10 ⁹ spores AF36 from 28 seeds kept at 31°C, 100% relative humidity for 7 days.	C. Schaffer 2/20/1996		
		446261-01	Unlikely that microbial contaminants or unintentional ingredients will be present at significant levels in the final product.	M. Watson 3/29/99		
	A-16		Color, odor, appearance: smells, looks and has the color of wheat seeds.			
	A-10	437634-05	Product Performance	C. Schaffer 2/20/96		
	52A-10	437634-03	Safety Data			
	56A-3					
	52B-10	439724-01?	Acute Oral. LD ₅₀ > 5000 mg/kg. 5 male, 5 female Sprague Dawley treated with <i>killed</i> microbial pesticide (500 mg/ml or 6.3 x 10 ³ CFU/ml). Observed at 2 and 4 hours post dosing, daily for 14 days thereafter. 1 female lost body weight (bw) from day 1 to day 8. Others gained bw throughout the study. No clinical signs, no abnormalities noted during study.	C. Schaffer 4/23/96	IV	
		439724-02?				
		439724-03				

CONCURRENCES

Gdln #	MRID #	Study	DER	Toxicity Category	Action required
154A-22	437634-03 437634-05	Safety Data Product Performance	Gail Tonimatsu 4/24/96		Information supports waiving data requirement for non-target plant. <i>A. flavus</i> ubiquitous on wide variety of live and decaying materials. Data raises concern for adverse risks to nontarget mammalian and avian species and honeybees.
154A-16	Data Waiver Request	Non-target Organism Environmental Safety. Non-target plant testing addressed	Doug Gurian- Sherman 6/23/99		Stomach content of birds in cotton fields indicate that birds do not eat cotton seeds. However, wheat seeds (carrier for AF36) are avian food source. Need acute avian oral and pulmonary, bee hive studies, soil and air monitoring data. Wild mammal studies can be addressed by acute oral and pulmonary mammalian studies for health effects.
154A-16 154A-17 154A-19 154A-20 154A-22 154A-23 154A-24	444779-01	Non-target Organism Environmental Safety Requirements Avian Ecological Risk Assessment (surrogate study using Chlofenapyr in cotton)	Doug Gurian- Sherman 6/23/99		Non-target FW and marine aquatic invertebrate studies may be waived based on location of cotton fields and lack of exposures above background levels.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

United States Environmental Protection Agency

JUN 20 2003

MEMORANDUM

SUBJECT: Consideration of a conditional registration of the active ingredient *Aspergillus flavus* AF36 (PC Code 006456, EPA Registration Number 71693-R) for use on cotton in Arizona and Texas, and an exemption from tolerance for cotton and its food/feed commodities associated with the use of this active ingredient (Pesticide Petition 8E5001).

----- **DECISION MEMORANDUM** -----

FROM: Janet L. Andersen, Director *Janet L. Andersen*
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs

TO: James Jones, Director
Office of Pesticide Programs

ISSUE

Should the Agency grant a conditional registration under FIFRA § 3(c)(7)(C) for the new microbial active ingredient, *Aspergillus flavus* strain AF36 (PC Code 006456, EPA Registration Number 71693-R) as an antifungal pesticide to reduce aflatoxin-producing colonies of *A. flavus* on cotton in Arizona and Texas?

Also, should the Agency grant an exemption from tolerance for residues of the active ingredient, *Aspergillus flavus* strain AF36, on cotton and its food/feed commodities as requested in Pesticide Petition 8E5001?

APPLICANT INFORMATION

The application for the use of this new active ingredient, *Aspergillus flavus* AF36, and the Pesticide Petition 8E5001 were filed by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390, on behalf of Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, Arizona 85040-2933.

SB:006456:71693R:7511C:06172003

CONCURRENCES

SYMBOL	7511C	7511C	7511C					
SURNAME	<i>BACHUS</i>	<i>Schuhay</i>	<i>KUTAN</i>					
DATE	<i>6/17/03</i>	<i>6/18/03</i>	<i>6/19/03</i>					

ROUTING & TRANSMITTAL SLIP

June 17, 2003

TO: (Name, office symbol, room number, building,
Agency Post)

Initials

Date

1 James Jones/Dir. OPP

JJ

6/23

2.

3.

4. Return to:

5. Shan Baochao

Action	Title	Note And Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	X Signature
Coordination	Justify	X Initials/Concurrence

REMARKS

Attached for your concurrence, and signature, are:

1. *Aspergillus flavus* AF36 Biopesticide Registration Action Document
2. Decision Memo for Office Director Concurrence
3. Federal Register Final Rule for Exemption from Tolerance for Office Dir. Signature.
4. Plain English Fact Sheet for *A. flavus* AF36

This is a conditional registration of a new active ingredient for use on cotton in Arizona and Texas.

FROM: (Name, org. symbol, Agency Post)

Janet Andersen/Dir. BPPD

Room No.-Bldg.
9th Floor-CM2Phone No
703-308-8712

Jim - We have O&C Concurrence even on the BRAD, but not in package and Shan is out today. Let Phil or Dennis know if you need it as Jim is out until Thursday in Brussels. Jack

RECEIVED

JUN 20 2003

4575

DIRECTOR, OFFICE OF PESTICIDE PROGRAM

BACKGROUND AND CONCLUSIONS

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed available and submitted data and information regarding the proposed use of *Aspergillus flavus* AF36, a non-aflatoxin-producing (atoxicogenic) strain of *A. flavus*. Evaluations of the data and conclusions are summarized and discussed in the attached Biopesticide Registration Action Document (BRAD). *Aspergillus flavus* AF36 (also called AF36) is to be applied at less than 0.01 lb of the active ingredient per acre. The applicant proposes a single, seasonal, prebloom application to cotton fields in Arizona and Texas. AF36 apparently displaces aflatoxin-producing strains of *A. flavus* from cotton fields and cotton, with a potential concomitant reduction of aflatoxin, a public health hazard. There is no other pesticide registered for the reduction of aflatoxin-producing colonies of *A. flavus*. For these reasons, *Aspergillus flavus* AF36 qualifies for an automatic presumptive finding for a conditional registration, and its use is presumed to be in the public interest. Sufficient data are available to support granting a conditional registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

While there are data gaps, the available and submitted data, which have been reviewed, comply with the Food Quality Protection Act of 1996. The health effects database support an exemption from tolerance for residues of *Aspergillus flavus* strain AF36 in/on cotton and its food/feed commodities. No toxicity endpoints were identified to justify setting a numerical tolerance for *A. flavus* AF36. Cotton itself is not a dietary commodity and residues of AF36 are not likely to survive the processing of cottonseed into its oil or meal. Thus, secondary transfer of AF36 to meat and milk are not likely to occur. Even if there was any potential aflatoxin associated with the use of AF36, in/on cotton food/feed commodities, those levels must meet the aflatoxin standards regulated by the Food and Drug Administration. Dietary, non-occupational dermal and inhalation exposures, as well as cumulative and aggregate exposures and risks are not likely to be greater than those which currently exist to the naturally occurring *A. flavus* strains. Thus, minimal to non-existent risks via dietary or non-occupational dermal and inhalation exposures are expected.

The applicant requested that data be waived for acute dermal toxicity/pathogenicity, primary dermal irritation, primary eye irritation, intraperitoneal and immune response studies. BPPD accepted the rationales submitted by the applicant to waive these data requirements. The justifications included (a) the non-toxic, non-infective acute oral and pulmonary effects, (b) a low application rate, (c) minimal to no pesticide drift based on the granular nature of the pesticide, (d) the ubiquitous occurrence of *Aspergillus* fungi, and (e) exposures which are not likely to be above background levels.

BPPD has not identified any acute, subchronic, chronic, immune, endocrine or dietary exposure issues that might affect human adults, infants and children. Because there are no threshold effects of concern to human adults, infants and children, when AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. Thus, there is a reasonable certainty of no incremental adverse effects to human adults, infants and children, and to the environment from the use of this active ingredient. Potential occupational exposure is mitigated by use of appropriate Personal Protective Equipment as required by the Worker Protection Standards.

Submitted data indicate no potential incremental adverse effects to avian and honey bee

non-target organisms. Soil and air monitoring data demonstrate that application of AF36 does not increase the total *A. flavus* in treated areas. AF36 may incite significant changes in the incidence of the toxigenic *A. flavus* strains resident in the agroecosystem. Justifications in support of data waiver requests for avian oral, freshwater and marine vertebrates and invertebrates, non-target plants and other non-target organisms were acceptable. Based on submitted avian and mammalian studies, exposures of AF36 to endangered avian and mammalian species and to wildlife are not likely to pose any incremental adverse effects.

CONDITIONS OF REGISTRATION

The remaining data, analyses of 5 production batches, are due within 30 months of registration. These conditions include (a) certification of the nominal limits of the active ingredient, identification and quantification of microbial contaminants and unintentional ingredients, a confirmatory method to identify AF36, storage and viability data, from 5 production batches; and (b) efficacy trial in Texas. If the applicant wishes to register other uses, additional data will be required on a case by case basis.

The applicant has committed to providing the data required to proceed to an unconditional Section 3(c)(5) registration. BPPD recommends in favor of a conditional registration and an exemption from tolerance on cotton food/feed commodities for the new microbial active ingredient, *Aspergillus flavus* strain AF36.

OFFICE DIRECTOR CONCURRENCE

Based on the discussion above and the summarized data evaluations in the attached BRAD, BPPD recommends that the microbial pesticide containing the new active ingredient *Aspergillus flavus* strain AF36 (PC Code 006456) be conditionally registered under 3(c)(7)(C) of FIFRA for use on cotton in Arizona and Texas.

BPPD also recommends that an exemption from tolerance for residues of *Aspergillus flavus* strain AF36 on cotton food/feed commodity be granted to the applicant, on the basis of the review of the health effects data, which comply with the requirements of the Food Quality Protection Act of 1996.

Concurrence: _____

/s/

Non Concurrence: _____

Date: _____

6/23/03



Chris Kaczmarek

06/12/03 06:31 PM

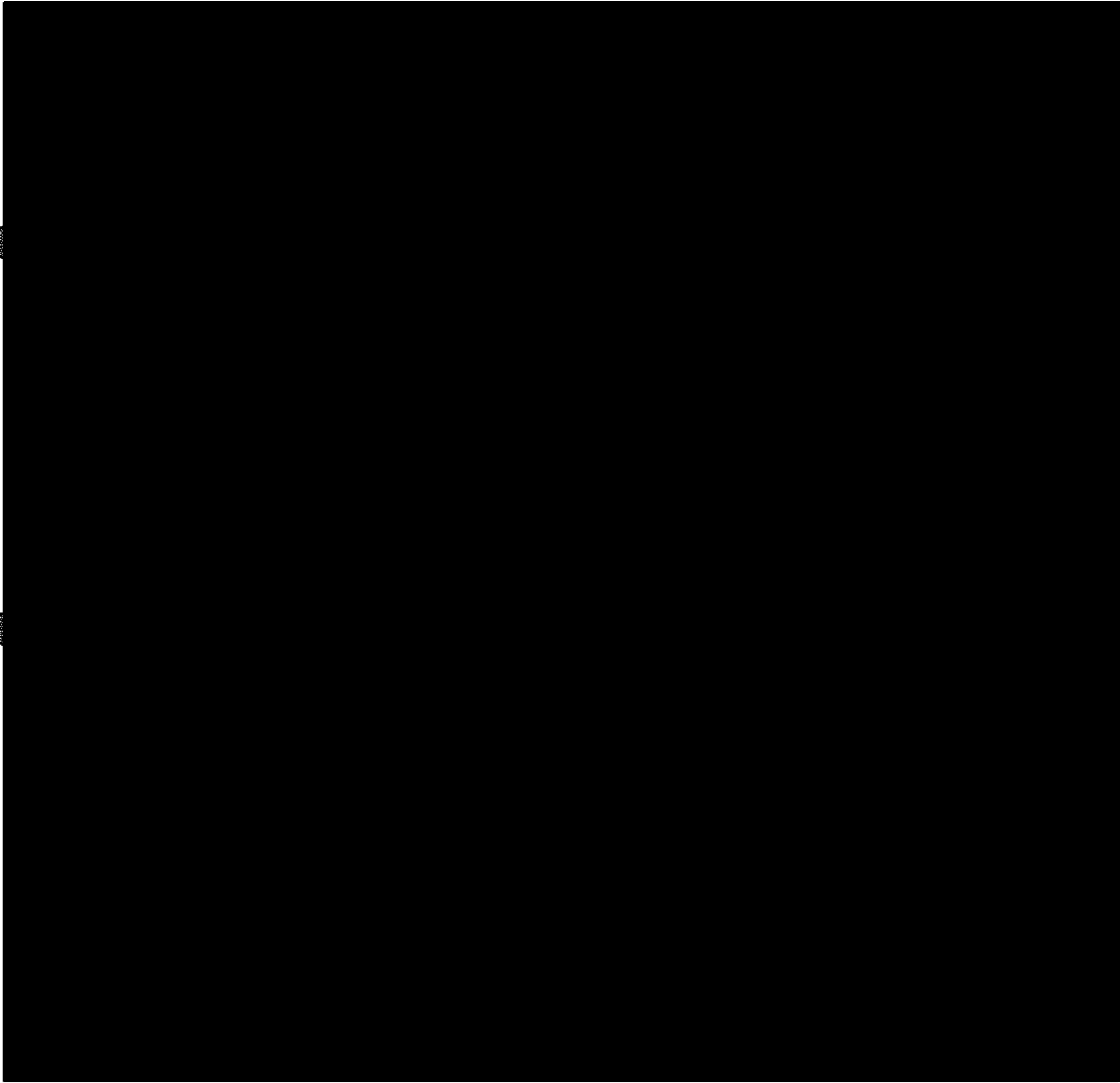
To: Shanaz Bacchus/DC/USEPA/US@EPA

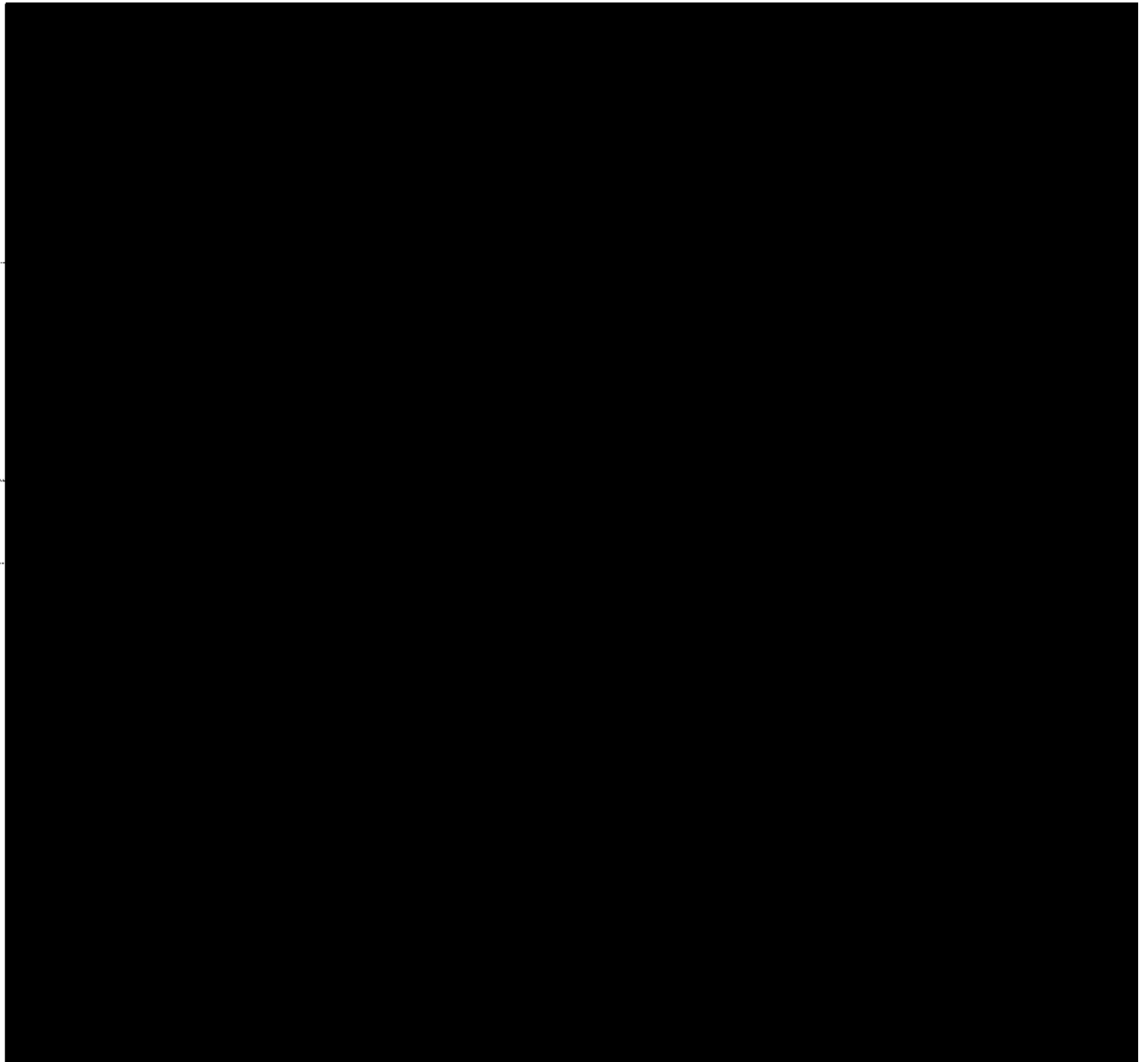
CC:

Subject: AF36 BRAD

*Deliberative
Attorney-Client Communication
Attorney Work Product*

Shawn,





Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel
(202) 564-3909



John Kough

06/10/03 03:12 PM

To: Chris Kaczmarek/DC/USEPA/US@EPA, Shanaz

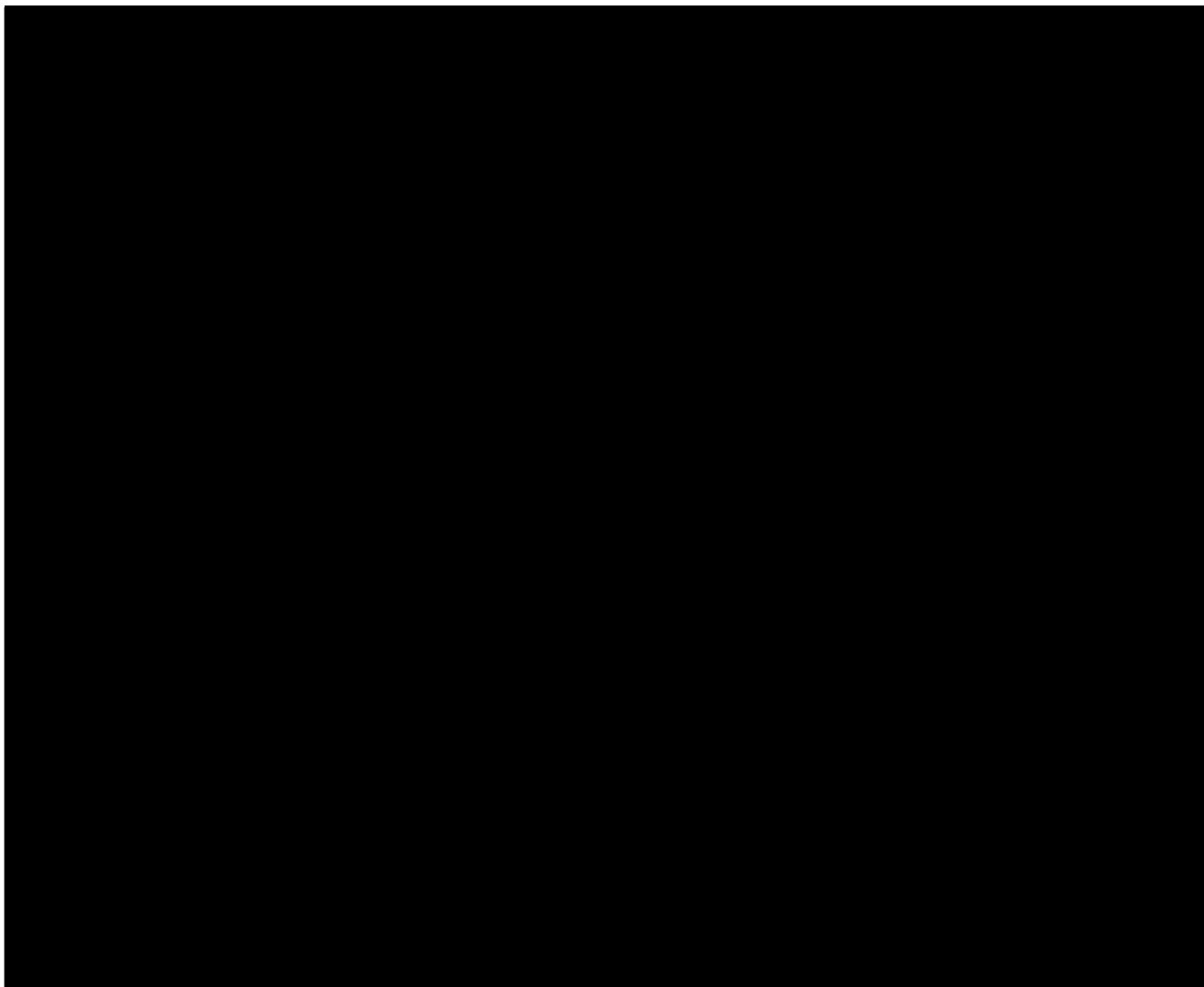
Bacchus/DC/USEPA/US@EPA, Carl Etsitty/DC/USEPA/US@EPA

cc: Phil Hutton/DC/USEPA/US@EPA, Dennis

Szuhay/DC/USEPA/US@EPA

Subject: mortality and vegetative compatibility in AF36

Chris,



John K.

ROUTING & TRANSMITTAL SLIP

July 2, 2003

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1 Jim Jones		
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Action	File	Note And Remm
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As Requested	For Correction	Prepare Reply
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Comment	Investigate	X Signature
Coordination	Justify	Initials, Concurrence

REMARKS

Aspergillus flavus AF36

FINAL RULE: EXEMPTION FROM TOLERANCE

Attached for your signature is a corrected copy of the Final Rule sent by the Federal Register office

The FR office wanted to make the corrections and have a clear new signature on the corrected copy. The supporting funds appropriation documents remain unchanged, so the old date (6/23/03) is accurate and appropriate for this document.

Thanks

RECEIVED

JUL 09 2003

4602

DIRECTOR, OFFICE OF PESTICIDE PROGRAMS

FROM (Name, org symbol, Agency/Post)

Janet Andersen, Dir. BPPD

Room No -Bldg.
910W38-CM2Phone No
703-308-8712

ACTION: R SCREEN: REQL USERID: SHUI

06/25/03 . 01:10:04 PM

*** REQUISITION ACCOUNTING LINE INQUIRY TABLE ***

KEY IS TRANS CODE, REQ NO, LINE NO

TRANS CODE: RQ

REQ NO: 0332JF3022

01- LINE NO: 001	BFY: 2003 2004	APPR: B	RPIO: 20	
BUDGET ORG: 32N00QB	PE: 40102C	LINE AMT:	1,853.00	
COST ORG:	SITE/PROJ:	CLOSED AMT:	0.00	
BOC: 2413	RPTG CATG:	OBLG AMT:	0.00	
LAST CHG STATUS:	DESCRIPTION: FRL-7311-6	ASPERGILLUS FLAVUS		
02- LINE NO:	BFY:	APPR:	RPIO:	
BUDGET ORG:	PE:	LINE AMT:		
COST ORG:	SITE/PROJ:	CLOSED AMT:		
BOC:	RPTG CATG:	OBLG AMT:		
LAST CHG STATUS:	DESCRIPTION:			
03- LINE NO:	BFY:	APPR:	RPIO:	
BUDGET ORG:	PE:	LINE AMT:		
COST ORG:	SITE/PROJ:	CLOSED AMT:		
BOC:	RPTG CATG:	OBLG AMT:		
LAST CHG STATUS:	DESCRIPTION:			

02-*L009 HEADER CHANGE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

Memorandum

SUBJECT: Cost of Publishing Documents in the Federal Register

FROM: John A. Richards, Director, OPPTS Federal Register Staff (7104T)

TO: OPPTS Document Drafters

In view of the limited amount of money that will be available for publishing documents in the Federal Register in the current fiscal year, the OPPTS Federal Register Staff is cooperating with budget and program personnel by keeping you informed of printing costs.

This document when prepared with electronic encoding will bill as follows:

Document OPPTS No.: 03P-0854

Pages/columns: 17

Approximate cost: \$ 1,853

We are furnishing this information so that you will be better able to allocate your funds during the remainder of the fiscal year. Unless a deliberate decision is made to withhold this document from publication, it will be forwarded automatically for publication upon its receipt after signature by my office. A hold can be placed on actual publication by calling the Federal Register Staff on (566-1580) prior to signature, and providing alternate instructions.

For OPPTS FR Staff Use Only

Expedited (Check One)		Templated Documents				Shell Documents				Adj. Value
		Text Pages		Tables		Text Pages		Tables		
Yes	No	Initial Text	Revised Text	Initial Text	Revised Text	Initial Text	Revised Text	Initial Text	Revised Text	
	✓	17								



United States
Environmental Protection Agency
Washington, DC 20460

FEDERAL REGISTER TYPESETTING REQUEST

Requestor: Complete Items 1, 2, 7, 8, 9, 10, 11, 12 and 13. Retain copy number 7 and submit the balance with manuscript copy to the Hq. Federal Register Office.
HQ Federal Register Office: Complete Items 3, 4, 6 and 8. Retain copy number 8 and submit balance to Hq. Printing Management.

1. TITLE OPP-2003-0138 Aspergillus flavus AF36: EXEMPTION FROM TOLERANCE

2. SUBMITTING ACTIVITY

3. ASSIGNED FRL NUMBER (include alpha & numeric characters for identification.)
7311-6

4. OPEN REQUISITION NUMBER

5. BILLING CODE
6560-50-S

6. FORWARDED TO GSA, NARS - SIGNATURE

DATE

7. NUMBER OF MANUSCRIPT PAGES

8. ESTIMATED NUMBER OF COLUMNS

9. ESTIMATED COST

17

\$ 1,853

10. SIGNATURE OF REQUESTING OFFICER

11. SIGNATURE OF FEDERAL REGISTER DESIGNEE

Janet L. Andersen, Ph.D., Director, BPPD

Pamela Landis

DATE

(a) TELEPHONE NUMBER

703-308-8712

(b) DATE

6-25-03

(c) TELEPHONE NUMBER

703-308-7013

12. FUNDS ARE AVAILABLE

Pamela Landis

NAME OF FUNDS CERTIFYING OFFICER

S. Diana Hudson

SIGNATURE OF FUNDS CERTIFYING OFFICER

703-308-7013

PHONE NUMBER OF FUNDS CERTIFYING OFFICER

03P-854

Emily

This document was submitted with sgml tags and is eligible for the 35% typesetting discount.

13. Financial and Accounting Data

Line	OCN (Max 8)	Budget/FY (Max 4)	Appropriation Code (Max 8)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)
1	JF3022	03 04	B	32N00QB	40102C	2413
2						
3						

Line	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1	\$1,853.00	00		
2				
3				

SFO

27

(Max 2)

Attachment #2: OPPTS Docket Verification and Certification Form



U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
(OPPTS)

1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action: *Final Rule Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance*

RIN #: 2070-

Docket ID #: *OPP-2003-0138*

FRL#:

Contact Information:

Name: *Shanaz Bacchus*Phone: *703-308-8097*

Legacy Information:

OPP2003-0048, OPP2003-0020

Program Lead's Verification: I have reviewed the docket and verified the following:

- ☐ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- ☐ Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.
- ☐ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.

☒ Comments: *no support document*

Date: *4/2/03*Initials: *Shanaz Bacchus*Phone: *703-308-8097*

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- ☐ The Docket ID # identified above matches our records.
- ☐ The documents identified in the attached Docket Index have been received by the Docket.
- ☐ The documents have been properly processed for inclusion in EPA Dockets, as appropriate.
- ☐ The documents either already are in the docket or are being process for inclusion in the docket.

☒ Comments: *NO Support doc.*

Date: *4-2-03*Signature: *[Signature]*Phone: *305-6434*

Program Lead's Certification: I hereby certify that:

- ☐ I have completed the verification above.
- ☐ I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.
- ☐ I have obtained the DM's sign-off.
- ☐ The docket is complete and ready for public release.

☒ Comments: *No support doc*

Date: *4/2/03*Signature: *[Signature]*Phone: *703-308-8097*

Attachment #2: OPPTS Docket Verification and Certification Form



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OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
(OPPTS)

1200 Pennsylvania Avenue, N.W. , Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action: *Final Rule: Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance*

RIN #: 2070-

Docket ID #: *OPP-2003-0138*

FRL#:

Contact Information:

Name: *Shanez Bacchus*Phone: *703-308-8097*

Legacy Information:

OPP2003-0048, OPP2003-0020

Program Lead's Verification: I have reviewed the docket and verified the following:

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- ☐ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.
- ☒ Comments: *no support document*

Date: *4/2/03*Initials: *Shanez Bacchus*Phone: *703-308-8097*

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- ☐ The Docket ID # identified above matches our records.
- ☐ The documents identified in the attached Docket Index have been received by the Docket.
- ☐ The documents have been properly processed for inclusion in EPA Dockets, as appropriate.
- ☒ The documents either already are in the docket or are being process for inclusion in the docket.
- ☒ Comments: *NO Support doc.*

Date: *4-2-03*Signature: *[Signature]*Phone: *305-6434*

Program Lead's Certification: I hereby certify that:

- ☐ I have completed the verification above.
- ☐ I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.
- ☐ I have obtained the DM's sign-off.
- ☐ The docket is complete and ready for public release.
- ☒ Comments: *No support doc*

Date: *4/2/03*Signature: *[Signature]*Phone: *703-308-8097*

[Federal Register: July 14, 2003 (Volume 68, Number 134)]

[Rules and Regulations]

[Page 41535-41541]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr14jy03-8]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0138; FRL-7311-6]

Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial antifungal agent *Aspergillus flavus* AF36, a non-aflatoxin-producing member of the naturally-occurring genus of fungi *Aspergillus*, in or on the food/feed commodity cotton, when the pesticide is used according to its label instructions as a prebloom application. The Interregional Research Project Number 4 (IR-4), on behalf of the Arizona Cotton Research and Protection Council, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

DATES: This regulation is effective July 14, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0138, must be received on or before September 12, 2003.

ADDRESSES: Written objections and hearing requests may be submitted by mail or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- o Crop production (NAICS code 111)
- o Animal production (NAICS code 112)
- o Food manufacturing (NAICS code 311)
- o Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0138. The official public docket is intended to serve as a repository for materials (i.e., documents and other information) submitted to the Agency in connection with this action and/or relied upon by the Agency in

[[Page 41536]]

taking this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The

official public docket is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. To the extent that a particular document is not located in the official public docket, consult the person listed under FOR FURTHER INFORMATION CONTACT.

The legacy docket for this case is OPP-2003-0020, which was set up in connection with the Notice of Filing of this pesticide petition, 8E5001. It contains the Federal Register Notice dated February 14, 2003, (68 FR 7554), which was published to announce this petition, other relevant Federal Register documents associated with the exemption from temporary tolerance which preceded this permanent exemption from tolerance, and comments received in response to the publication of this petition.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the Federal Register of February 14, 2003 (68 FR 7554) (FRL-7289-9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 8E5001) by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U. S. Highway #1

South, North Brunswick, NJ 08902-3390, on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, AZ 85040-2933. This notice included a summary of the petition prepared by the petitioner, IR-4, on behalf of the Arizona Cotton Research and Protection Council. In response to the notice of filing of this petition, comments in favor of the use of the pesticide were received from cotton growers, processors and ginner, mainly from Arizona and Texas.

The petition requested that 40 CFR 180.1206 be amended by establishing an exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Aspergillus flavus AF36 (also referred to as AF36) is a non-aflatoxin-producing or atoxigenic strain of *Aspergillus flavus*, whose species are ubiquitous around the world. Some members of the genus *Aspergillus* produce mycotoxins, such as aflatoxin, a potent carcinogen produced by toxigenic strains of *A. flavus*. Other members of the genus *Aspergillus* have been domesticated for commercial use, such as *Aspergillus niger* for production of enzymes (e.g., alpha-galactosidase found in beano, a dietary supplement) and *Aspergillus oryzae* for production of soy sauce. The subject strain of this final rule, *Aspergillus flavus* AF36, is characterized as an atoxigenic strain by its lack of production of aflatoxin. It is not vegetatively compatible with the toxigenic strains of *A. flavus*, a feature which limits cross-over potential to, and, thus, further proliferation of, the toxigenic strains. Starter cultures, selected on the basis of the vegetative incompatibility with aflatoxin-producing strains, are to be monitored by standard thin layer chromatography (TLC) procedures, and visualization via scanning fluorescence densitometry scanning [Master Record Identification Number (MRID) 44626101; BPPD Data Evaluation Report of Analysis of Samples, dated March 29, 1999 (hereinafter referred to as "BPPD review - March 29, 1999"); BPPD Review of Supplementary Information dated May 14, 1999 (hereinafter referred to as "BPPD review - May 14, 1999")]. In this manner, the applicant proposes to maintain batches free of aflatoxin contamination during production. Batches contaminated with aflatoxin, or human pathogens, or unintentional ingredients above regulatory levels are to be destroyed. Thus, use of AF36 is not likely to add to the environmental burden of the aflatoxin-producing strains of *A. flavus*.

The pesticide is proposed for a single prebloom application once a year to cotton fields to displace the aflatoxin-producing strains of *Aspergillus flavus* from cotton. Sterilized wheat seeds, colonized with *Aspergillus flavus* AF36,

[[Page 41537]]

are to be applied at 10 lb of end-use product (EP) (equivalent to the low rate of less than 0.01 lb active ingredient (ai) per acre). Within 3 days of application of the pesticide, the fields are furrow irrigated to promote germination of AF36, which apparently colonizes the cotton crop and soil, before the aflatoxin-producing strains of *A. flavus* proliferate. This competitive exclusion of the aflatoxin-producing strains does not increase the total *Aspergillus* population in the environment above background levels as demonstrated in soil and air monitoring studies. [MRIDs 45307201, 45307202; BPPD Review of Soil and Air Monitoring Studies and Product Performance Testing (Efficacy), dated May 15, 2003 (hereinafter referred to as "BPPD Review - May 15,

2003"]]. The displacement of the toxigenic strain of *Aspergillus flavus* by AF36 may reduce aflatoxin contamination of cotton seed.

The toxicology and pathogenicity data generated by the petitioner in support of this tolerance exemption, and reviewed by the Agency, are summarized below. The following discussion of the evaluations of the submitted studies and information indicates that exposure to the pesticide is not likely to be greater than that which occurs normally to other ubiquitous *A. flavus* strains. Submitted data also indicate no toxicity or infectivity of AF36 in test mammalian systems. More detailed analyses of these studies can be found in the specific Agency reviews of the studies that are cited below.

1. Acute oral toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3050; MRID 43972403). Agency evaluation of submitted acute oral study indicates no toxicity/infectivity effects of the pesticide. Five male, and five female Sprague Dawley rats were treated orally with the microbial pesticide (500 milligrams/milliliter (mg/mL) or 6.3×10^3 cfu/mL) by gavage. No clinical signs or abnormalities were noted during the study, and the pesticide was considered to be neither toxic nor infective following oral administration of a single dose. The acute oral test resulted in a Toxicity Category IV classification with a lethal dose (LD) > 50 greater than 5,000 milligrams/kilogram (mg/kg) body weight [MRID 43972403; BPPD Data Evaluation Report, Acute Oral Toxicity Study in Rats, dated April 23, 1996 (hereinafter referred to as "BPPD Review - April 23, 1996")].

2. Acute pulmonary toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3150; MRID 45798201). The Agency required an intratracheal pulmonary infectivity/pathogenicity study. This test involves intratracheal instillation of the test material and post mortem examination of lungs and other organs for clearance.

Three studies were submitted in support of the mammalian acute infectivity/pathogenicity pulmonary guideline: A range finding study and two complete acute pulmonary studies. The dose-range study concluded that 10^8 cfu/rat would be a suitable test dose level for the acute pulmonary studies [MRID 45739101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as "BPPD Review - April 02, 2003a")]. In the first acute pulmonary study, conducted with Tween 80 as a surfactant in the test material, 26 male and 26 female Sprague Dawley rats (approximately 8 to 10 weeks old) each were dosed with a single intratracheal dose of 1.2 mL/kg at 5.30×10^8 cfu/mL (or 1.28 to 1.63×10^8 cfu/animal). Results from this study indicated that the test organism was neither infective nor pathogenic, in spite of rat mortality, which is believed to have been due to a severe acute inflammatory response to the Tween 80 [MRID 45798101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as "BPPD Review - April 02,

2003b")].

In the second acute pulmonary study, which was a repetition of the first acute pulmonary test, but was conducted without Tween 80, 25 male and 25 female Sprague Dawley rats (approximately 8 to 10 weeks old) each received a single intratracheal dose of approximately 1.2 mL/kg. Mortality of 4 rats by day 2 appeared to be attributable to an initial dosing effect. The rest of the test animals showed an initial response, followed by a rapid recovery indicating no toxicity. Although some surviving rats lost weight intermittently, all surviving rats gained weight prior to scheduled sacrifice. No clinical signs that were considered to be due to the test organism were observed in the test rats. Organs were examined post mortem as previously described. *Aspergillus flavus* AF36 was detected in the lungs with clearance by day 8 after dosing. No test organisms were detected in any samples from the shelf control or inactivated test organism treated rats. Based on the presented/submitted data, including the clearance data, the test organism, *Aspergillus flavus* AF36, was considered not toxic, infective, or pathogenic to the rat pulmonary system. The study is acceptable.

3. Acute inhalation (OPPTS Harmonized Guideline 152-32). The inert is sterilized wheat seeds, comprising approximately 99% of this pesticidal product. It acts as a matrix and nutrient source for the germinating AF36. Because this constitutes the majority of the pesticide and does not contain respirable particles of less than 10 microns, an inhalation study was not required pursuant to 40 CFR 158.740(c). In addition, based on the results obtained through the acute pulmonary toxicity/pathogenicity studies summarized immediately above, AF36 is considered not toxic, infective, or pathogenic to the rat pulmonary system. On the basis of this study and the nature of the inert ingredients present, the pesticide was considered Toxicity Category III for acute inhalation effects. [MRID 45798201; BPPD Data Evaluation Report, dated April 02, 2003c (hereinafter referred to as "BPPD Review - April 02, 2003c")].

4. Hypersensitivity incidents (OPPTS Harmonized Guideline 152-37; MRID 45739104). The registrant submitted information (MRID 45739104) to demonstrate the lack of hypersensitivity to workers who have been exposed during the manufacture, application, and use of the pesticide in the research and experimental phases. No adverse hypersensitivity reaction to AF36 was recorded or reported by a state council or six companies during use for 3 or 6 years [MRID 45739104; BPPD Data Evaluation Report, dated April 02, 2003d (hereinafter referred to as "BPPD Review - April 02, 2003d")]. However, to comply with the Agency's requirements under section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

5. Data waivers. Data waivers were requested for the following

studies:

- i. Acute dermal toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3100)
- ii. Primary dermal irritation (OPPTS Harmonized Guideline 870.2500)
- iii. Primary eye irritation (OPPTS Harmonized Guideline 870.2400)
- iv. Intravenous, intracerebral, intraperitoneal injection (OPPTS Harmonized Guideline 885.3200)
- v. Hypersensitivity study (40 CFR 152-36)
- vi. Immune response (40 CFR 152-38)

With regards to the dermal and eye irritation guideline tests, it was impractical to apply the end-use product, sterilized wheat seeds inoculated with *Aspergillus flavus* AF36, as test material. Furthermore, non-occupational dermal and eye exposures, or exposures via any of the routes in Unit III.5.i.-vi., are not likely to be above naturally-occurring background levels for the following reasons.

First, *Aspergillus flavus*, a saprophytic fungus, is a normal

[[Page 41538]]

constituent of the microflora in air and soil. The naturally occurring soil and plant colonizer is also found on living and dead plant material throughout the world. Aflatoxin-producing strains of *Aspergillus flavus* are particularly prominent in hot, dry climates supplemented with irrigation and are ubiquitous components of the natural Arizona desert ecosystem. Quantities of *A. flavus* typically increase during crop production and the fungus occurs widely on crop debris left in the soil. Shortly after application, AF36 germinates, apparently displaces the aflatoxin-producing strains from cotton and the soil, and spore levels return to normal background, without increase of total *A. flavus*. This was demonstrated in soil and air monitoring studies submitted over multiple years of experimental usage [BPPD Review - May 15, 2003]. Thus exposures to AF36 are not likely to increase above those normally associated with the naturally occurring *A. flavus* background levels.

Second, the application rate is low, being less than 0.01 lb active ingredient per acre, and agricultural sites are treated, thus minimizing non-occupational and residential exposure. The proposed label rate is less than 0.01 pound of active ingredient in 10 pounds end-use product, or approximately 1.34×10^7 colony forming units (cfu) per acre.

Finally, drift is not expected during application based on the large granular nature of the pesticide (i.e., sterilized inoculated wheat seeds). In addition, only one prebloom application is made, and cultivation is not recommended after application. Thus, once again, the potential for non-occupational dermal and residential exposure is

unlikely.

The acute oral toxicological study demonstrated an LD₅₀ of greater than 5,000 mg/kg with no toxicity/infectivity effects, and demonstrable clearance from organs examined post mortem [MRID 43972403; BPPD Review - April 23, 1996]. This rationale supported the request to waive the acute intraperitoneal study.

A hypersensitivity study was waived since hypersensitivity incidents were not reported from maximally exposed workers and researchers during the research and experimental phases associated with the use of the active ingredient, *A. flavus* AF36 [BPPD Review - April 02, 2003d]. Nevertheless, reports of hypersensitivity incidents associated with the use of the pesticide are still required to comply with FIFRA section 6(a)(2) requirements.

Submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) also indicate that following oral and pulmonary routes of exposure [BPPD Review - April 23, 1996; BPPD Review - April 02, 2003c], the immune system is still intact and able to process and clear the active ingredient. Thus, the request to waive the immune response study was granted.

On the basis of the foregoing rationales, and there being no documented problems associated with the non-aflatoxin producing strain, *Aspergillus flavus* AF36, data waivers for the studies listed in Unit III.5.i.-vi., were granted to the applicant for the proposed use of *Aspergillus flavus* AF36 on cotton.

6. Subchronic, chronic toxicity and oncogenicity, and residue. Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is a potential for aggregate exposure of adult humans, infants and children to the microbe because of the ubiquitous distribution of *Aspergillus* fungal strains in the environment. The Agency has considered the incremental exposure and risk associated with the proposed application of this strain of *Aspergillus flavus*, AF36, as

summarized below, and concludes that use of AF36 is not likely to add an incremental risk above that posed by the normal exposure of adults, infants and children to *Aspergillus flavus* strains present in the environment. In fact, use of the pesticide, AF36, may decrease potential environmental aflatoxin exposure to exposed populations.

A. Dietary Exposure

1. Food. Based on submitted studies, the end-use product, *Aspergillus flavus* AF36, demonstrates low acute oral toxicity category IV potential [BPPD Review - April 23, 1996]. No toxicity endpoints were indicated to justify setting a numerical tolerance for the fungal active ingredient, *Aspergillus flavus* AF36. An LD₅₀ greater than 5,000 mg/kg body weight, in the acute oral studies discussed above, indicates that consumption of food commodities treated with AF36 poses no incremental risk via dietary exposure. Indeed, the submitted data indicate no toxicity or infectivity of AF36 in the acute oral test mammalian systems.

Cotton itself is not a food commodity. Residues of *A. flavus* AF36, the microbial active ingredient, are not likely to survive the heating and pressure associated with the processing of cottonseed into cottonseed meal. Moreover, *A. flavus* AF36 will not separate into the edible fraction, cotton seed oil. Thus, potential transfer of residues of *A. flavus* AF36 to edible cotton food/feed commodities is not expected. Consequently, human dietary exposure to *A. flavus* AF36 via cottonseed oil, or by secondary transfer of *A. flavus* AF36 residues to meat and milk via cottonseed meal, is not expected. Therefore, the Agency has determined that dietary exposure to *A. flavus* AF36 is not likely to result in any undue health effects and risk.

While the Agency has concluded that AF36 is not likely to add to the dietary burden, any potential contribution by AF36 to aflatoxin contamination was also considered, for a conservative estimate of the health effects of this pesticide. This is because aflatoxin is considered a public health hazard (see Unit VII.D.) and AF36 is proposed as a biocontrol agent for aflatoxin-producing strains of *A. flavus*. Even if AF36 does not control aflatoxin levels in the treated cotton food/feed commodities, a safety net exists in the screening of cotton and its by-products for aflatoxin prior to their introduction into the channels of commerce. For instance, FDA does not allow cotton seed products containing aflatoxin above 20 parts per billion (ppb) to be used in dairy rations or above 300 ppb to be used for feeding beef cattle. As previously stated, the registrant claims that quality control and selection procedures will not allow aflatoxin production in the starter cultures for pesticide manufacture [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Any batches with aflatoxin are to be

destroyed. For these reasons, the Agency has determined that use of AF36 will not add to the dietary burden of aflatoxin, but is rather more likely to ameliorate aflatoxin levels in treated cotton food/feed commodities. Therefore, dietary exposure to aflatoxin, as a result of AF36 use, is not likely to be greater, and may even be less, than that which currently exists.

[[Page 41539]]

2. Drinking water exposure. Exposure to AF36 via drinking water is not likely to be greater than current/existing exposures to *A. flavus* strains. Potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, percolation through soil. Thus, exposure via drinking water from the proposed use of this non-aflatoxin-producing strain of *Aspergillus flavus* is not likely to pose any incremental risk to adult humans, infants and children. In fact, displacement of the toxigenic strains of *A. flavus* by AF36 may decrease exposure and risk to the toxigenic strains of *A. flavus* in the environment.

B. Other Non-Occupational Exposure

1. Dermal exposure. The potential for non-occupational dermal exposure to AF36 is unlikely because the potential use sites, are commercial and agricultural, and because of the granular nature of the pesticide, which minimizes spray drift. As discussed earlier (see Unit III.), lack of hypersensitivity incidents, low application rates, and return of levels of *Aspergillus flavus* to background shortly after germination, poses minimal risk to populations via dermal, non-occupational exposure. Thus, dermal non-occupational exposure to the non-aflatoxin strain is not likely to be greater than the existing exposure to *A. flavus* at current levels.

2. Inhalation exposure. For the reasons stated immediately above, non-occupational inhalation exposure to AF36 is not expected to be greater than that which currently exists for *A. flavus* strains.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *Aspergillus flavus* AF36 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *Aspergillus flavus* AF36 does not appear to be toxic or pathogenic to humans. There is no indication that the fungus *A. flavus* AF36 shares any common mechanisms of toxicity with other

registered pesticides. In addition, there are no other registered pesticide products containing *Aspergillus flavus* AF36, and other *A. flavus* strains abound naturally in the environment. Moreover, the displacement of the toxigenic strain of *A. flavus* by AF36 may reduce aflatoxin contamination of cottonseed. Based on the low toxicity potential of AF36, the fact that it is non-aflatoxigenic, and the safety net already in place to monitor for aflatoxin, no cumulative or incremental effect is expected from the use of AF36 on cotton.

VI. Determination of Safety for U.S. Population, Infants and Children

There is reasonable certainty that no harm will result from aggregate exposures to residues of *A. flavus* AF36, in its use as an antifungal agent, to the U. S. population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm, from this fungus in its use as an antifungal agent via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (see Unit III above). Moreover, non-occupational inhalation or dermal exposure is not expected above background levels (see Unit V).

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that the fungus, *A. flavus* AF36, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when *A. flavus* AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *A. flavus* AF36.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including

all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen-and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority, to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of this active ingredient, *Aspergillus flavus* AF36, at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this microorganism. The submitted toxicity/infectivity or pathogenicity studies in the rodent (required for microbial pesticides) indicate that, following oral and pulmonary routes of exposure, the immune system is still intact and able to process and clear the active ingredient (see Unit III.). In addition, based on the low potential exposure level associated with the proposed single, seasonal, prebloom application of the pesticide, the Agency expects no adverse effects to the endocrine or immune systems.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Accordingly, the Agency has concluded that for an exemption from tolerance, analytical methods are not needed for enforcement purposes for residues of *Aspergillus flavus* AF36 on treated cotton. Nonetheless, and for purposes of clarification, analytical methods are still required for product characterization, quality control, and quality assurance for manufacturing purposes [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Vegetative compatibility tests are used to screen starter cultures to identify the non-aflatoxin-producing *Aspergillus flavus* AF36 strain. Starter cultures of AF36 are also selected on the basis of

[[Page 41540]]

the lack of aflatoxin as monitored by standard thin layer chromatography (tlc) procedures and visualization via scanning fluorescence densitometry scanning. Other appropriate methods are required for quality control to assure product characterization, the control of human pathogens and other unintentional metabolites or ingredients within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

C. Codex Maximum Residue Level

There is no Codex maximum residue level for residues of *Aspergillus flavus* AF36.

D. Efficacy Data

PR Notice 2002-1 lists aflatoxin as a public health hazard, for which product performance or efficacy data are required according to 40 CFR 158.202(i). To demonstrate that this pesticide may reduce aflatoxin-producing strains and does not increase *A. flavus* populations above background levels, the applicant provided product performance or efficacy data from multiple years of soil and air monitoring studies.

Aflatoxin, one of the most potent human carcinogens, is the metabolite of concern produced by the target pest, aflatoxin-producing strains of *Aspergillus flavus*. As such, the Agency considers aflatoxin a public health hazard. In the soils of cotton-producing areas of Arizona and south Texas, especially in the dry regions, the toxigenic strains are prominent. Few alternatives, if any, exist to displace aflatoxin-producing *A. flavus* strains from cotton and other crops. Decontamination of crops via ammoniation is costly, not available universally, and decreases the value of the crop. Other methods to reduce aflatoxin formation include manipulation of harvest date, costly irrigation practices, and different methods of harvesting and storage practices.

Efficacy data submitted to the Agency include monitoring of soil and air levels of the toxigenic and non-aflatoxin-producing strains of *A. flavus* AF36 in the field and on the crops. Results from the environmental expression and population monitoring studies, during the experimental program, demonstrate that a single seasonal application of AF36 on cotton fields may incite significant changes in the incidence of toxigenic *A. flavus* strains resident in the agroecosystem, without altering the overall quantity of *A. flavus*. Soil and air population counts of *A. flavus* from treated fields were associated with concomitant decreases in incidences of toxigenic *A. flavus*, for many of the treated areas [BPPD review - May 15, 2003]. Reducing the aflatoxin-producing populations of fungi, and the concomitant reduction of

aflatoxin, a potent carcinogen, is in the public interest.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0138 in the subject line on the first page of your submission. All objections and hearing requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 12, 2003.

1. Filing the request. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921

Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tomkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. Copies for the Docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0138, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit

[[Page 41541]]

I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of

your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption from the tolerance requirement in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition,

the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 2, 2003.

James Jones,
Director, Office of Pesticide Programs.

ø Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

ø 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

ø 2. Section 180.1206 is revised to read as follows:

Sec. 180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

[FR Doc. 03-17726 Filed 7-11-03; 8:45 am]
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Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

[Federal Register: February 14, 2003 (Volume 68, Number 31)]

[Notices]

[Page 7554-7558]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr14fe03-90]

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0020; FRL-7289-9]

Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide microbial agent in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2003-0020, must be received on or before March 17, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0020. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that

are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly

[[Page 7555]]

available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. EPA Dockets. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0020. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. E-mail. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP-2003-0020. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file

format. Avoid the use of special characters and any form of encryption.

2. By mail. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2003-0020.

3. By hand delivery or courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2003-0020. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.

[[Page 7556]]

4. If you estimate potential burden or costs, explain how you

arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and record keeping requirements.

Dated: February 6, 2003.

Phil Hutton,
Acting Director, Biopesticides and Pollution Prevention Division,
Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 and The Arizona Cotton Research and Protection Council

PP 8E5001

EPA has received a pesticide petition (PP 8E5001) from Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue Phoenix, Arizona 85040-2933 proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.1206 by establishing an amendment/expansion of an existing tolerance exemption for the microbial pesticide *Aspergillus flavus* AF36 in or on the food and feed commodity cotton and its by products.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, the aforesaid Interregional Research Project Number 4 (IR-4), has submitted the following summary of information, data, and arguments in support of the pesticide petition on behalf of the Arizona Cotton Research and Protection Council, however EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product name and Proposed Use Practices

Aspergillus flavus AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, is proposed for application to cotton to reduce the incidence of aflatoxin producing strains of *Aspergillus flavus* and thereby reduce aflatoxin contamination of cottonseed. When applied just prior to flowering, *Aspergillus flavus* AF36 which does not produce aflatoxin, competitively excludes aflatoxin producing *Aspergillus flavus* strains without increasing *Aspergillus flavus* in the environment in the long term. Sterile wheat seed colonized with *Aspergillus flavus* AF36 is applied at 10 lb of end-use product (total amount of active ingredient less than 0.01 lb/acre) per acre. The pesticide is currently being used in certain counties in the States of Arizona and Texas under an Experimental Use Permit (EPA Reg. No. 69224-EUP-1). The current submission proposes to establish a permanent exemption from tolerance for residues of *Aspergillus flavus* AF36 on cotton and its byproducts.

B. Product Identity/Chemistry

I. Identity of the pesticide and corresponding residues. The pesticide and corresponding residues are identified as *Aspergillus flavus* AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*.

2. Magnitude of residue at the time of harvest and method used to determine the residue. *Aspergillus flavus* AF36 is a naturally occurring fungus isolated from cottonseed produced in the Yuma Valley of Arizona. *Aspergillus flavus* AF36 has been shown to be naturally and consistently associated with commercial cotton grown in Arizona. Other than immediately after application, the overall quantity of *Aspergillus flavus* at time of harvest on cottonseed grown in fields where *Aspergillus flavus* AF36 has been applied and has been shown to be similar to levels on cottonseed grown in fields where no application was made. *Aspergillus flavus* is a widespread fungus. It is particularly well adapted to the hot desert regions of Arizona where it is widespread in the environment. The communities of *Aspergillus flavus* in the desert and in agricultural fields are naturally composed of both aflatoxin producing (toxigenic) and aflatoxin non-producing (atoxigenic) strains. Both atoxigenic and toxigenic strains have been found on essentially all plant material and soils in the desert valleys of Arizona. The goal of applications is to increase the percent of the *Aspergillus flavus* community composed of the atoxigenic strain AF36 and to decrease the percent of *Aspergillus flavus* that produces aflatoxins on the crop and in the fields.

3. A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed. An exemption from the requirement of a tolerance for residues of the microbial pesticide *Aspergillus flavus* AF36 in/on cotton is being proposed for cotton treated in Arizona and Texas. *Aspergillus flavus* isolate AF36, when applied to the soil just prior to bloom has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Aflatoxin levels in cottonseed products are regulated by the Food and Drug Administration (FDA). FDA does not allow cottonseed products containing aflatoxin at 20 parts per billion (ppb), or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin above 300 ppb, to be used for feeding beef cattle. All lots of the active ingredient (*Aspergillus flavus* isolate AF36) and the formulated products are monitored for aflatoxin production as part of a rigorous quality control program. Starter cultures of *Aspergillus flavus* isolate AF36 used in the production of the end-use product are always screened for strain identity by vegetative

[[Page 7557]]

compatibility, and for aflatoxin production using thin layer chromatography and appropriate standards. Quality control standards are zero tolerance in the starter cultures and in the formulated product for aflatoxin production, and for *Aspergillus flavus* not identified as

Aspergillus flavus isolate AF36. Aspergillus flavus AF36 has never been found to produce aflatoxin.

C. Mammalian Toxicological Profile

An acute oral toxicity test was performed whereby a single oral dose of 5,000 milligrams/kilogram body weight (mg/kg/bwt) per animal of Aspergillus flavus AF36 colonized wheat seed was administered by gavage to five male and five female Sprague Dawley rats. The oral LD50 of Aspergillus flavus AF36 was determined to be greater than 5,000 mg/kg rat body weight. No clinical signs were observed during the 14-day study and no abnormalities or adverse effects were observed in any of the rats upon necropsy.

An initial pulmonary rat study resulted in lethality in a significant number of animals treated with either the live Aspergillus flavus AF36 in Tween 80 or heat killed Aspergillus flavus AF36 in Tween 80. Onset of symptoms was rapid after dosing with all deaths occurring by day 4 of the study. All rats surviving to day 4 of the study recovered and all rats sacrificed (as scheduled) on day 8 or day 15 of the study had totally eliminated viable Aspergillus flavus AF36 from the lungs, caecal contents, and feces. There was no evidence of infectivity. The aetiology of deaths was unclear. It appeared that Aspergillus flavus AF36 prepared as a test substance with Tween 80 caused a severe acute inflammatory response. Retrospective literature review and consultation with a toxicologist supported the theory that the responses were a result of a synergism with Tween 80 and/or of Tween 80 breakdown products formed during preparation of the spore suspension test substance.

A second rat pulmonary study was therefore undertaken. In the second study the conidia were both washed from the wheat and suspended in sterile physiological saline instead of Tween 80. Animals (2 male and 2 female for each treatment level) were dosed at 0, 10⁵, 10⁶, 10⁷, and 10⁸ colony forming units per rat. There were no clinical signs in any of the treatment groups considered to be associated with the test substance. Rats were sacrificed at day 8 without treatment associated mortality. No abnormalities were observed in any of the animals at the macroscopic examination at termination.

Based on these two mammalian studies, the petitioner concludes that Aspergillus flavus AF36 does not present either a toxicological or an infectious risk to mammals. Data waivers were requested for the following toxicology studies: Acute dermal toxicology/pathology, primary dermal irritation, primary eye irritation, and acute intraperitoneal toxicology/pathology effects of the microbial pesticide. The following rationales were used as a basis for the data waiver requests:

- Researchers and other workers have worked with *Aspergillus flavus* AF36 at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to 1998) and in hand-picked field plots (1989 to 1994) without report of any adverse health effects.

- *Aspergillus flavus* AF36 is widely distributed in the environment and its occurrence is natural.

- The label will require applicators and other handlers to wear Personal Protective Equipment (PPE) such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks, and goggles, to mitigate against dermal and primary eye irritation exposure.

The pesticide is to be applied aurally by mixers/handlers and applicators who are licensed and trained to handle restricted materials. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre. Applications of AF36 do not significantly impact the total amount of *Aspergillus flavus* in the soil or crop, but only change the proportion of the AF36 strain in relation to the overall soil population. Since the product is applied to cotton fields as a granular formulation on colonized wheat seeds, exposure from drift is minimal.

In addition, the following rationales were advanced in support of the data waiver requests for acute dermal toxicity and primary dermal irritation. These studies were waived during the experimental use program, based upon the lack of toxicity in animals dosed orally. While other *Aspergillus flavus* strains have been reported to be dermal sensitizers, this testing is not warranted, since the aerial method of application and the PPE required on the label will mitigate dermal exposure to workers and pesticide handlers. The acute intraperitoneal study was waived based upon the lack of toxicity in animals dosed orally and by pulmonary/intratracheal instillation.

Genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity testing were not performed, since no adverse effects were observed in the acute toxicology study Tier I studies. Tier II (885.3550), subchronic toxicology study (EPA OPPTS 885.3600) and chronic feeding studies (guideline 152-50) are only required if triggered by adverse effects observed in Tier I studies.

D. Aggregate Exposure

1. Dietary exposure--i. Food. *Aspergillus flavus* AF36 is a naturally occurring organism, which does not produce aflatoxin and is thus safer than the aflatoxin-producing *Aspergillus flavus* isolates. Proposed uses and application rates will not result in increases in the total population of *Aspergillus flavus* on the mature crop beyond

naturally occurring background levels. FDA does not allow cottonseed products containing aflatoxin at 20 ppb or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin levels above 300 ppb, to be used for feeding beef cattle.

Aspergillus flavus AF36, when applied to the soil just prior to bloom, has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Furthermore, the proposed use and application rate will not increase exposure of humans to *Aspergillus flavus* by dietary means, since cotton itself is not a food product for human consumption. There is minimal dietary exposure to *Aspergillus flavus* from cottonseed. There is no mechanism for *Aspergillus flavus* to be transferred from the seed to animal products and there is no evidence that the fungus readily contaminates meat or milk. Seed is typically extracted for oil with hexane and that process kills the fungus. Furthermore, applications of *Aspergillus flavus* AF36 do not increase the indigenous populations of *Aspergillus flavus* associated with the harvested crop. The applications merely alter the composition of the fungal community associated with the mature crop so that aflatoxin producing strains are far less frequent. The result is a much lower incidence of aflatoxins in the crop and in the environment associated with the developing and mature crop.

ii. Drinking water. *Aspergillus flavus* AF36 is a naturally occurring organism that is already widespread in the environment and is not considered to be a risk to drinking water. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure of *Aspergillus flavus* through the drinking

[[Page 7558]]

water. Applications of *Aspergillus flavus* AF36 do not increase the long-term populations of *Aspergillus flavus* in the environment, and thus are not expected to influence the relationship of *Aspergillus flavus* to water sources. Applications merely change the composition of the *Aspergillus flavus* community so that aflatoxin producing strains are less common in the environment.

2. Non-dietary exposure. The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant and is not expected to present any risk of adverse health effects.

E. Cumulative Exposure

There are no other registered products containing *Aspergillus flavus* AF36 or any other isolates (strains) of the microbial active

ingredient. Data submitted show that the fungal metabolite of concern, which is aflatoxin, is not produced by *Aspergillus flavus* AF36 in the crop or in artificial media in the lab. When applied prior to flowering, *Aspergillus flavus* AF36 has been shown to exclude aflatoxin producing fungi competitively from the developing crop and to reduce aflatoxin contamination of cottonseed. Data show that the proposed use will not result in appreciable increases in the long-term population of *Aspergillus flavus* on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

F. Safety Determination

1. U.S. population. *Aspergillus flavus* AF36 is a naturally occurring organism. This isolate has low toxicity as demonstrated by the acute oral toxicity study in rats. *Aspergillus flavus* is ubiquitous throughout the hot desert valleys in Arizona. Studies have shown that treatment of cotton fields just prior to flowering with sterile wheat seed colonized by *Aspergillus flavus* AF36 at 10 lb per acre does not increase the long-term populations of *Aspergillus flavus* either on the crop at maturity or in the soil 1 year after application. Based on this information, Interregional Research Project Number-4 is of the opinion that the aggregate exposure to *Aspergillus flavus* over a lifetime should not change with application of *Aspergillus flavus* AF36, and exposure to both aflatoxin producing *Aspergillus flavus* strains and aflatoxin should decrease. This should be beneficial to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to *Aspergillus flavus* AF36.

2. Infants and children. Based on the lack of toxicity and natural occurrence, there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to *Aspergillus flavus* AF36. Exempting *Aspergillus flavus* AF36 from the requirement of a tolerance should pose no significant risk to humans or the environment.

G. Effects on the Immune and Endocrine Systems

Aspergillus flavus AF36 is a naturally occurring organism, which does not produce aflatoxin, and is thus safer than the *Aspergillus flavus* isolates that produce aflatoxin. To date there is no evidence to suggest that *Aspergillus flavus* AF36 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Efficacy

Existence of aflatoxins in the environment is a public health hazard. Data were submitted to demonstrate that proper use of *Aspergillus flavus* AF36 results in reductions in the average aflatoxin producing potential of fungi resident in treated areas and in reductions in the quantity of aflatoxins in crops. In field tests prior to 1996, the aflatoxin content of cottonseed was shown to be inversely related to the proportion of the *Aspergillus flavus* community on the crop composed of *Aspergillus flavus* AF36. Detailed analyses of the aflatoxin content of commercial fields from 1996 through 1998 confirmed that reduced aflatoxin levels were associated with displacement of aflatoxin producers by *Aspergillus flavus* AF36 from treated crops and that treatments were associated with up to 90% reductions in crop aflatoxin content.

Efficacy of applications of *Aspergillus flavus* AF36 in displacing aflatoxin producers was demonstrated for fungal communities both on cottonseed from treated crops at harvest and in soils of treated fields 1 year after treatment. This included cotton crops treated in 1996 (112 acres treated), 1997 (463 acres treated), 1998 (499 acres), 1999 (10,488 acres), 2000 (16,725 acres), and 2001 (19,975 acres treated). The proportion of *Aspergillus flavus* communities composed of *Aspergillus flavus* AF36 indicates the extent to which aflatoxin producers were displaced. In 1996 average incidence of AF36 on treated crops was 88.5% and in the soil, 1 year after treatment, incidence of AF36 was 85.2%. Incidences of AF36 on treated crops were 78% and 67% in 1997 and 1998, respectively, and in soil 1 year after treatment, AF36 incidences were 72% and 77%, respectively. Successful displacement was also observed as the acreage treated rapidly expanded from 1999 to 2001 with average incidences of AF36 on treated crops ranging from 57% in 1999 to 66% in 2001.

Aflatoxin-producing S strain isolates of *Aspergillus flavus* are prominent in soils of cotton producing areas of Arizona and south Texas. They produce more aflatoxins than other *Aspergillus flavus* isolates such as the non-aflatoxin-producing L strain *Aspergillus flavus* AF36. Applications of AF36 during the experimental program were effective at displacing the high aflatoxin producing S strain of *Aspergillus flavus*. During the course of the experimental use program, *Aspergillus flavus* AF36 also caused long-term reductions in the aflatoxin producing potential of fungal communities in agricultural fields. *Aspergillus flavus* AF36 retained atoxigenicity (failure to produce aflatoxins) upon repeated reisolation from treated fields 1, 2, or 3 years after treatment. Thus, there was a long-term reduction in the potential of fungal communities to produce aflatoxins in treated areas. The average aflatoxin producing potential of *Aspergillus flavus* communities resident in soils of treated fields was reduced on average 73% 1 year after treatment over the 3 year period (1996 to 1999). S

strain isolates, which produced very high levels of aflatoxins, with field averages ranging from 7,100 ppb, aflatoxin to 22,700 ppb, aflatoxin, were effectively displaced. Their incidence was reduced from initially composing 46% of *Aspergillus flavus* soil communities to composing on average of 11%.

I. Existing Tolerances

The registrant is not aware of any existing tolerances or tolerance exemptions for *Aspergillus flavus* AF36, other than the temporary tolerance exemption on cotton (40 CFR 180.1206) in conjunction with an EUP, which expires on December 30, 2004.

J. International Tolerances

There are no Codex maximum residue levels established for residues of *Aspergillus flavus* AF36. *Aspergillus flavus* AF36 containing products are presently not registered for pest control outside of the United States.

[FR Doc. 03-3696 Filed 2-13-03; 8:45 am]
BILLING CODE 6560-50-S

[Federal Register: March 12, 2003 (Volume 68, Number 48)]
[Notices]
[Page 11841-11843]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr12mr03-90]

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0048; FRL-7293-8]

Pesticide Product; Registration Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to register the pesticide product *Aspergillus flavus* AF36 containing a new active ingredient not included in any previously registered product pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments, identified by the docket ID number OPP-2003-0048, must be received on or before April 11, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or

[[Page 11842]]

pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- [bull] Crop production (NAICS 111)
- [bull] Animal production (NAICS 112)
- [bull] Food manufacturing (NAICS 311)
- [bull] Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0048. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may

use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public

use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public

comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand

delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. EPA Dockets. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments.

Once in the system, select "search," and then key in docket ID number OPP-2003-0048. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. E-mail. Comments may be sent by e-mail to opp-docket@epa.gov,

Attention: Docket ID Number OPP-2003-0048. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is

[[Page 11843]]

placed in the official public docket, and made available in EPA's electronic public docket.

iii. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit 1.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. By mail. Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC, 20460-0001, Attention: Docket ID Number OPP-2003-0048.

3. By hand delivery or courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall 2, 1921 Jefferson Davis Hwy., Arlington, VA., Attention: Docket ID Number OPP-2003-0048. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit 1.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the registration activity.

7. Make sure to submit your comments by the deadline in this notice.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. Registration Applications

EPA received an application as follows to register a pesticide product containing a new active ingredient not included in any previously registered product pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U. S. Highway 1 South, North Brunswick, NJ 08902-3390 on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, AZ 85040-2933, submitted an application, to register a new active ingredient for a naturally occurring microbial pesticide *Aspergillus flavus* AF36, (EPA File Symbol 71693-R), a non-aflatoxin-producing strain of *Aspergillus flavus*, to reduce aflatoxin contamination on cotton. *Aspergillus flavus* AF36 occurs naturally in Arizona and Texas.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: February 28, 2003.

Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division, Office of
Pesticide Programs.

[FR Doc. 03-5752 Filed 3-11-03; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0138; FRL-7311-6]

Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial antifungal agent *Aspergillus flavus* AF36, a non-aflatoxin-producing member of the naturally-occurring genus of fungi *Aspergillus*, in or on the food/feed commodity cotton, when the pesticide is used according to its label instructions as a prebloom application. The Interregional Research Project Number 4 (IR-4), on behalf of the Arizona Cotton Research and Protection Council, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities. ✓

DATES: This regulation is effective [insert date of publication in the Federal Register]. Objections and requests for hearings, identified by docket ID number OPP-2003-0138, must be received on or before [insert date 60 days after date of publication in the Federal Register].

ADDRESSES: Written objections and hearing requests may be submitted by mail or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: bacchus.shanaz@epa.gov.

OBP-854								
COMMENTS								
SYMBOL	7104T	7104T	7511C	7511C	7511C	7511C	7511C	7511C
SURNAME	E. Blom	J. P. Blom	Shanaz Bacchus	Kenneth	Page	Shanaz	Shanaz	Shanaz
DATE	5-30-2003	5/30/2003	6/3/2003	6/4/2003	6/16/03	6-18-03	6/19/03	6/19/03

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0138; FRL-7311-6]

Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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DATES: This regulation is effective *[insert date of publication in the Federal Register]*. Objections and requests for hearings, identified by docket ID number OPP-2003-0138, must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0138. The official public docket is intended to serve as a repository for materials (i.e., documents and other information) submitted to the Agency in connection with this action and/or relied upon by the Agency in taking this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. To the extent that a particular document is not located in the official public docket, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

The legacy docket for this case is OPP-2003-0020, which was set up in connection with the Notice of Filing of this pesticide petition, 8E5001. It contains the **Federal Register** Notice dated February 14, 2003, (68 FR 7554), which was published to announce this petition, other relevant **Federal Register** documents associated with the exemption from temporary tolerance which preceded this permanent exemption from tolerance, and comments received in response to the publication of this petition.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a

beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the Federal Register of February 14, 2003 (68 FR 7554) (FRL-7289-9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 8E5001) by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390, on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, AZ 85040-2933. This notice included a summary of the petition prepared by the petitioner, IR-4, on behalf of the Arizona Cotton Research and Protection Council. In response to the notice of filing of this petition, comments in favor of the use of the pesticide were received from cotton growers, processors and ginner, mainly from Arizona and Texas.

The petition requested that 40 CFR 180.1206 be amended by establishing an exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider "available information" concerning the cumulative

effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Aspergillus flavus AF36 (also referred to as AF36) is a non-aflatoxin-producing or atoxigenic strain of *Aspergillus flavus*, whose species are ubiquitous around the world. Some members of the genus *Aspergillus* produce mycotoxins, such as aflatoxin, a potent carcinogen produced by toxigenic strains of *A. flavus*. Other members of the genus *Aspergillus* have been domesticated for commercial use, such as *Aspergillus niger* for production of enzymes (e.g., alpha-galactosidase found in beano, a dietary supplement) and *Aspergillus oryzae* for production of soy sauce. The subject strain of this final rule, *Aspergillus flavus* AF36, is characterized as an atoxigenic strain by its lack of production of aflatoxin. It is not vegetatively compatible with the toxigenic strains of *A. flavus*, a feature which limits cross-over potential to, and, thus, further proliferation of, the toxigenic strains. Starter cultures, selected on the basis of the vegetative incompatibility with aflatoxin-producing strains, are to be monitored by standard thin layer chromatography (TLC) procedures, and visualization via scanning fluorescence densitometry scanning [Master Record Identification Number (MRID) 44626101; BPPD Data Evaluation Report of Analysis of Samples, dated March 29, 1999 (hereinafter referred to as "BPPD review - March 29, 1999"); BPPD Review of Supplementary Information dated May 14, 1999 (hereinafter referred to as "BPPD review - May 14, 1999")]. In this manner, the applicant proposes to maintain batches free of aflatoxin contamination during production. Batches contaminated with aflatoxin, or human pathogens, or unintentional ingredients above regulatory levels are to be destroyed. Thus, use of AF36 is not likely to add to the environmental burden of the aflatoxin-producing strains of *A. flavus*.

The pesticide is proposed for a single prebloom application once a year to cotton fields to displace the aflatoxin-producing strains of *Aspergillus flavus* from cotton. Sterilized wheat seeds, colonized with *Aspergillus flavus* AF36, are to be applied at 10 lb of end-use product

(EP) (equivalent to the low rate of less than 0.01 lb active ingredient (ai) per acre). Within 3 days of application of the pesticide, the fields are furrow irrigated to promote germination of AF36, which apparently colonizes the cotton crop and soil, before the aflatoxin-producing strains of *A. flavus* proliferate. This competitive exclusion of the aflatoxin-producing strains does not increase the total *Aspergillus* population in the environment above background levels as demonstrated in soil and air monitoring studies. [MRIDs 45307201, 45307202; BPPD Review of Soil and Air Monitoring Studies and Product Performance Testing (Efficacy), dated May 15, 2003 (hereinafter referred to as "BPPD Review - May 15, 2003")]. The displacement of the toxigenic strain of *Aspergillus flavus* by AF36 may reduce aflatoxin contamination of cotton seed.

The toxicology and pathogenicity data generated by the petitioner in support of this tolerance exemption, and reviewed by the Agency, are summarized below. The following discussion of the evaluations of the submitted studies and information indicates that exposure to the pesticide is not likely to be greater than that which occurs normally to other ubiquitous *A. flavus* strains. Submitted data also indicate no toxicity or infectivity of AF36 in test mammalian systems. More detailed analyses of these studies can be found in the specific Agency reviews of the studies that are cited below.

1. *Acute oral toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3050; MRID 43972403)*. Agency evaluation of submitted acute oral study indicates no toxicity/infectivity effects of the pesticide. Five male, and five female Sprague Dawley rats were treated orally with the microbial pesticide (500 milligrams/milliliter (mg/mL) or 6.3×10^3 cfu/mL) by gavage. No clinical signs or abnormalities were noted during the study, and the pesticide was considered to be neither toxic nor infective following oral administration of a single dose. The acute oral test resulted in a Toxicity Category IV classification with a lethal dose (LD)₅₀ greater than 5,000 milligrams/kilogram (mg/kg) body weight [MRID 43972403; BPPD Data Evaluation Report, Acute Oral Toxicity Study in Rats, dated April 23, 1996 (hereinafter referred to as "BPPD Review - April 23, 1996")].

2. *Acute pulmonary toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3150; MRID 45798201)*. The Agency required an intratracheal pulmonary infectivity/pathogenicity study. This test involves intratracheal instillation of the test material and post mortem examination of lungs and other organs for clearance.

Three studies were submitted in support of the mammalian acute infectivity/pathogenicity pulmonary guideline: A range finding study and two complete acute pulmonary studies. The dose-range study concluded that 10^8 cfu/rat would be a suitable test dose level for the acute pulmonary studies [MRID 45739101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as "BPPD Review

- April 02, 2003a'']. In the first acute pulmonary study, conducted with Tween 80 as a surfactant in the test material, 26 male and 26 female Sprague Dawley rats (approximately 8 to 10 weeks old) each were dosed with a single intratracheal dose of 1.2 mL/kg at 5.30×10^8 cfu/mL (or 1.28 to 1.63×10^8 cfu/animal). Results from this study indicated that the test organism was neither infective nor pathogenic, in spite of rat mortality, which is believed to have been due to a severe acute inflammatory response to the Tween 80 [MRID 45798101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as "BPPD Review - April 02, 2003b'')].

In the second acute pulmonary study, which was a repetition of the first acute pulmonary test, but was conducted without Tween 80, 25 male and 25 female Sprague Dawley rats (approximately 8 to 10 weeks old) each received a single intratracheal dose of approximately 1.2 mL/kg. Mortality of 4 rats by day 2 appeared to be attributable to an initial dosing effect. The rest of the test animals showed an initial response, followed by a rapid recovery indicating no toxicity. Although some surviving rats lost weight intermittently, all surviving rats gained weight prior to scheduled sacrifice. No clinical signs that were considered to be due to the test organism were observed in the test rats. Organs were examined *post mortem* as previously described. *Aspergillus flavus* AF36 was detected in the lungs with clearance by day 8 after dosing. No test organisms were detected in any samples from the shelf control or inactivated test organism treated rats. Based on the presented/submitted data, including the clearance data, the test organism, *Aspergillus flavus* AF36, was considered not toxic, infective, or pathogenic to the rat pulmonary system. The study is acceptable.

3. *Acute inhalation (OPPTS Harmonized Guideline 152-32)*. The inert is sterilized wheat seeds, comprising approximately 99% of this pesticidal product. It acts as a matrix and nutrient source for the germinating AF36. Because this constitutes the majority of the pesticide and does not contain respirable particles of less than 10 microns, an inhalation study was not required pursuant to 40 CFR 158.740(c). In addition, based on the results obtained through the acute pulmonary toxicity/pathogenicity studies summarized immediately above, AF36 is considered not toxic, infective, or pathogenic to the rat pulmonary system. On the basis of this study and the nature of the inert ingredients present, the pesticide was considered Toxicity Category III for acute inhalation effects. [MRID 45798201; BPPD Data Evaluation Report, dated April 02, 2003c (hereinafter referred to as "BPPD Review - April 02, 2003c'')].

4. *Hypersensitivity incidents (OPPTS Harmonized Guideline 152-37; MRID 45739104)*. The registrant submitted information (MRID 45739104) to demonstrate the lack of hypersensitivity to workers who have been exposed during the manufacture, application, and use of the pesticide in the research and experimental phases. No adverse hypersensitivity reaction to AF36 was recorded or reported by a state

council or six companies during use for 3 or 6 years [MRID 45739104; BPPD Data Evaluation Report, dated April 02, 2003d (hereinafter referred to as "BPPD Review - April 02, 2003d")]. However, to comply with the Agency's requirements under section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

5. *Data waivers.* Data waivers were requested for the following studies:

- i. Acute dermal toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3100)
- ii. Primary dermal irritation (OPPTS Harmonized Guideline 870.2500)
- iii. Primary eye irritation (OPPTS Harmonized Guideline 870.2400)
- iv. Intravenous, intracerebral, intraperitoneal injection (OPPTS Harmonized Guideline 885.3200)
- v. Hypersensitivity study (40 CFR 152-36)
- vi. Immune response (40 CFR 152-38)

With regards to the dermal and eye irritation guideline tests, it was impractical to apply the end-use product, sterilized wheat seeds inoculated with *Aspergillus flavus* AF36, as test material. Furthermore, non-occupational dermal and eye exposures, or exposures via any of the routes in Unit III.5.i.—vi., are not likely to be above naturally-occurring background levels for the following reasons.

First, *Aspergillus flavus*, a saprophytic fungus, is a normal constituent of the microflora in air and soil. The naturally occurring soil and plant colonizer is also found on living and dead plant material throughout the world. Aflatoxin-producing strains of *Aspergillus flavus* are particularly prominent in hot, dry climates supplemented with irrigation and are ubiquitous components of the natural Arizona desert ecosystem. Quantities of *A. flavus* typically increase during crop production and the fungus occurs widely on crop debris left in the soil. Shortly after application, AF36 germinates, apparently displaces the aflatoxin-producing strains from cotton and the soil, and spore levels return to normal background, without increase of total *A. flavus*. This was demonstrated in soil and air monitoring studies submitted over multiple years of experimental usage [BPPD Review - May 15, 2003]. Thus exposures to AF36 are not likely to increase above those normally associated with the naturally occurring *A. flavus* background levels.

Second, the application rate is low, being less than 0.01 lb active ingredient per acre, and agricultural sites are treated, thus minimizing non-occupational and residential exposure. The proposed label rate is

less than 0.01 pound of active ingredient in 10 pounds end-use product, or approximately 1.34×10^7 colony forming units (cfu) per acre.

Finally, drift is not expected during application based on the large granular nature of the pesticide (i.e., sterilized inoculated wheat seeds). In addition, only one prebloom application is made, and cultivation is not recommended after application. Thus, once again, the potential for non-occupational dermal and residential exposure is unlikely.

The acute oral toxicological study demonstrated an LD₅₀ of greater than 5,000 mg/kg with no toxicity/infectivity effects, and demonstrable clearance from organs examined *post mortem* [MRID 43972403; BPPD Review - April 23, 1996]. This rationale supported the request to waive the acute intraperitoneal study.

A hypersensitivity study was waived since hypersensitivity incidents were not reported from maximally exposed workers and researchers during the research and experimental phases associated with the use of the active ingredient, *A. flavus* AF36 [BPPD Review - April 02, 2003d]. Nevertheless, reports of hypersensitivity incidents associated with the use of the pesticide are still required to comply with FIFRA section 6(a)(2) requirements.

Submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) also indicate that following oral and pulmonary routes of exposure [BPPD Review - April 23, 1996; BPPD Review - April 02, 2003c], the immune system is still intact and able to process and clear the active ingredient. Thus, the request to waive the immune response study was granted.

On the basis of the foregoing rationales, and there being no documented problems associated with the non-aflatoxin producing strain, *Aspergillus flavus* AF36, data waivers for the studies listed in Unit III.5.i.—vi., were granted to the applicant for the proposed use of *Aspergillus flavus* AF36 on cotton.

6. *Subchronic, chronic toxicity and oncogenicity, and residue.*

Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is a potential for aggregate exposure of adult humans, infants and children to the microbe because of the ubiquitous distribution of *Aspergillus* fungal strains in the environment. The Agency has considered the incremental exposure and risk associated with the proposed application of this strain of *Aspergillus flavus*, AF36, as summarized below, and concludes that use of AF36 is not likely to add an incremental risk above that posed by the normal exposure of adults, infants and children to *Aspergillus flavus* strains present in the environment. In fact, use of the pesticide, AF36, may decrease potential environmental aflatoxin exposure to exposed populations.

A. Dietary Exposure

1. *Food.* Based on submitted studies, the end-use product, *Aspergillus flavus* AF36, demonstrates low acute oral toxicity category IV potential [BPPD Review - April 23, 1996]. No toxicity endpoints were indicated to justify setting a numerical tolerance for the fungal active ingredient, *Aspergillus flavus* AF36. An LD₅₀ greater than 5,000 mg/kg body weight, in the acute oral studies discussed above, indicates that consumption of food commodities treated with AF36 poses no incremental risk via dietary exposure. Indeed, the submitted data indicate no toxicity or infectivity of AF36 in the acute oral test mammalian systems.

Cotton itself is not a food commodity. Residues of *A. flavus* AF36, the microbial active ingredient, are not likely to survive the heating and pressure associated with the processing of cottonseed into cottonseed meal. Moreover, *A. flavus* AF36 will not separate into the edible fraction, cotton seed oil. Thus, potential transfer of residues of *A. flavus* AF36 to edible cotton food/feed commodities is not expected. Consequently, human dietary exposure to *A. flavus* AF36 via cottonseed oil, or by secondary transfer of *A. flavus* AF36 residues to meat and milk via cottonseed meal, is not expected. Therefore, the Agency has determined that dietary exposure to *A. flavus* AF36 is not likely to result in any undue health effects and risk.

While the Agency has concluded that AF36 is not likely to add to the dietary burden, any potential contribution by AF36 to aflatoxin contamination was also considered, for a conservative estimate of the health effects of this pesticide. This is because aflatoxin is considered a public health hazard (see Unit VII.D.) and AF36 is proposed as a biocontrol agent for aflatoxin-producing strains of *A. flavus*. Even if AF36 does not control aflatoxin levels in the treated cotton food/feed commodities, a safety net exists in the screening of cotton and its by-products for aflatoxin prior to their introduction into the channels of commerce. For instance, FDA does not allow cotton seed products containing aflatoxin above 20 parts per billion (ppb) to be used in dairy rations or above 300 ppb to be used for feeding beef cattle. As previously stated, the registrant claims that quality control and selection procedures will not allow aflatoxin production in the starter cultures

for pesticide manufacture [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Any batches with aflatoxin are to be destroyed. For these reasons, the Agency has determined that use of AF36 will not add to the dietary burden of aflatoxin, but is rather more likely to ameliorate aflatoxin levels in treated cotton food/feed commodities. Therefore, dietary exposure to aflatoxin, as a result of AF36 use, is not likely to be greater, and may even be less, than that which currently exists.

2. *Drinking water exposure.* Exposure to AF36 via drinking water is not likely to be greater than current/existing exposures to *A. flavus* strains. Potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, percolation through soil. Thus, exposure via drinking water from the proposed use of this non-aflatoxin-producing strain of *Aspergillus flavus* is not likely to pose any incremental risk to adult humans, infants and children. In fact, displacement of the toxigenic strains of *A. flavus* by AF36 may decrease exposure and risk to the toxigenic strains of *A. flavus* in the environment.

B. Other Non-Occupational Exposure

1. *Dermal exposure.* The potential for non-occupational dermal exposure to AF36 is unlikely because the potential use sites, are commercial and agricultural, and because of the granular nature of the pesticide, which minimizes spray drift. As discussed earlier (see Unit III.), lack of hypersensitivity incidents, low application rates, and return of levels of *Aspergillus flavus* to background shortly after germination, poses minimal risk to populations via dermal, non-occupational exposure. Thus, dermal non-occupational exposure to the non-aflatoxin strain is not likely to be greater than the existing exposure to *A. flavus* at current levels.

2. *Inhalation exposure.* For the reasons stated immediately above, non-occupational inhalation exposure to AF36 is not expected to be greater than that which currently exists for *A. flavus* strains.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *Aspergillus flavus* AF36 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *Aspergillus flavus* AF36 does not appear to be toxic or pathogenic to humans. There is no indication that the fungus *A. flavus* AF36 shares any common mechanisms of toxicity with other registered pesticides. In addition, there are no other registered pesticide products containing *Aspergillus flavus* AF36, and other *A. flavus* strains abound naturally in the environment. Moreover, the displacement of the toxigenic strain of *A. flavus* by AF36 may reduce aflatoxin contamination of cottonseed. Based on the low toxicity

potential of AF36, the fact that it is non-aflatoxigenic, and the safety net already in place to monitor for aflatoxin, no cumulative or incremental effect is expected from the use of AF36 on cotton.

VI. Determination of Safety for U.S. Population, Infants and Children

There is reasonable certainty that no harm will result from aggregate exposures to residues of *A. flavus* AF36, in its use as an antifungal agent, to the U. S. population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm, from this fungus in its use as an antifungal agent via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (see Unit III above). Moreover, non-occupational inhalation or dermal exposure is not expected above background levels (see Unit V).

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that the fungus, *A. flavus* AF36, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when *A. flavus* AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *A. flavus* AF36.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen-and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority, to require the wildlife evaluations. As the

science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of this active ingredient, *Aspergillus flavus* AF36, at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this microorganism. The submitted toxicity/infectivity or pathogenicity studies in the rodent (required for microbial pesticides) indicate that, following oral and pulmonary routes of exposure, the immune system is still intact and able to process and clear the active ingredient (see Unit III.). In addition, based on the low potential exposure level associated with the proposed single, seasonal, prebloom application of the pesticide, the Agency expects no adverse effects to the endocrine or immune systems.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Accordingly, the Agency has concluded that for an exemption from tolerance, analytical methods are not needed for enforcement purposes for residues of *Aspergillus flavus* AF36 on treated cotton. Nonetheless, and for purposes of clarification, analytical methods are still required for product characterization, quality control, and quality assurance for manufacturing purposes [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Vegetative compatibility tests are used to screen starter cultures to identify the non-aflatoxin-producing *Aspergillus flavus* AF36 strain. Starter cultures of AF36 are also selected on the basis of the lack of aflatoxin as monitored by standard thin layer chromatography (tlc) procedures and visualization via scanning fluorescence densitometry scanning. Other appropriate methods are required for quality control to assure product characterization, the control of human pathogens and other unintentional metabolites or ingredients within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

C. Codex Maximum Residue Level

There is no Codex maximum residue level for residues of *Aspergillus flavus* AF36.

D. Efficacy Data

PR Notice 2002-1 lists aflatoxin as a public health hazard, for which product performance or efficacy data are required according to 40 CFR 158.202(i). To demonstrate that this pesticide may reduce aflatoxin-producing strains and does not increase *A. flavus* populations above

background levels, the applicant provided product performance or efficacy data from multiple years of soil and air monitoring studies.

Aflatoxin, one of the most potent human carcinogens, is the metabolite of concern produced by the target pest, aflatoxin-producing strains of *Aspergillus flavus*. As such, the Agency considers aflatoxin a public health hazard. In the soils of cotton-producing areas of Arizona and south Texas, especially in the dry regions, the toxigenic strains are prominent. Few alternatives, if any, exist to displace aflatoxin-producing *A. flavus* strains from cotton and other crops. Decontamination of crops via ammoniation is costly, not available universally, and decreases the value of the crop. Other methods to reduce aflatoxin formation include manipulation of harvest date, costly irrigation practices, and different methods of harvesting and storage practices.

Efficacy data submitted to the Agency include monitoring of soil and air levels of the toxigenic and non-aflatoxin-producing strains of *A. flavus* AF36 in the field and on the crops. Results from the environmental expression and population monitoring studies, during the experimental program, demonstrate that a single seasonal application of AF36 on cotton fields may incite significant changes in the incidence of toxigenic *A. flavus* strains resident in the agroecosystem, without altering the overall quantity of *A. flavus*. Soil and air population counts of *A. flavus* from treated fields were associated with concomitant decreases in incidences of toxigenic *A. flavus*, for many of the treated areas [BPPD review - May 15, 2003]. Reducing the aflatoxin-producing populations of fungi, and the concomitant reduction of aflatoxin, a potent carcinogen, is in the public interest.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0138 in the subject line on the first page of your submission. All objections and hearing requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before *[insert date 60 days after date of publication in the Federal Register]*.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0138, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order

12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption from the tolerance requirement in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

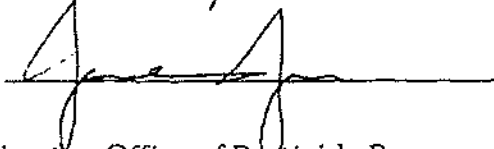
X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,
Agricultural commodities, Pesticides and pests, Reporting and
recordkeeping requirements.

Dated: 7/2/03

A handwritten signature in black ink, appearing to be 'J. Michael', is written over a horizontal line.

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1206 is revised to read as follows:

§ 180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

BILLING CODE 6560-50-S

ROUTING & TRANSMITTAL SLIP

July 2, 2003

TO: {Name, office symbol, room number, building, Agency Post}	Initials	Date
1 Janet Andersen		
2.		
3.		
4.		
5.		

Action	File	Note And Return
Approval	For Clearance	X Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	Initials, Concurrence

REMARKS

Aspergillus flavus AF36

FINAL RULE: EXEMPTION FROM TOLERANCE

Attached for Jim Jones' signature is a corrected copy of the Final Rule sent by the Federal Register office

The FR office wanted to make the corrections and have a clear new signature on the corrected copy. The supporting funds appropriation documents remain unchanged, so the old date (6/23/03) is accurate and appropriate for this document.

Thanks

FROM: {Name, org. symbol, Agency Post}	Room No.-Bldg. 910W38-CM2
Shanaz Bacchus	Phone No 703-308-8097

CONCURRENCES					
SYMBOL					
SURNAME					
DATE					



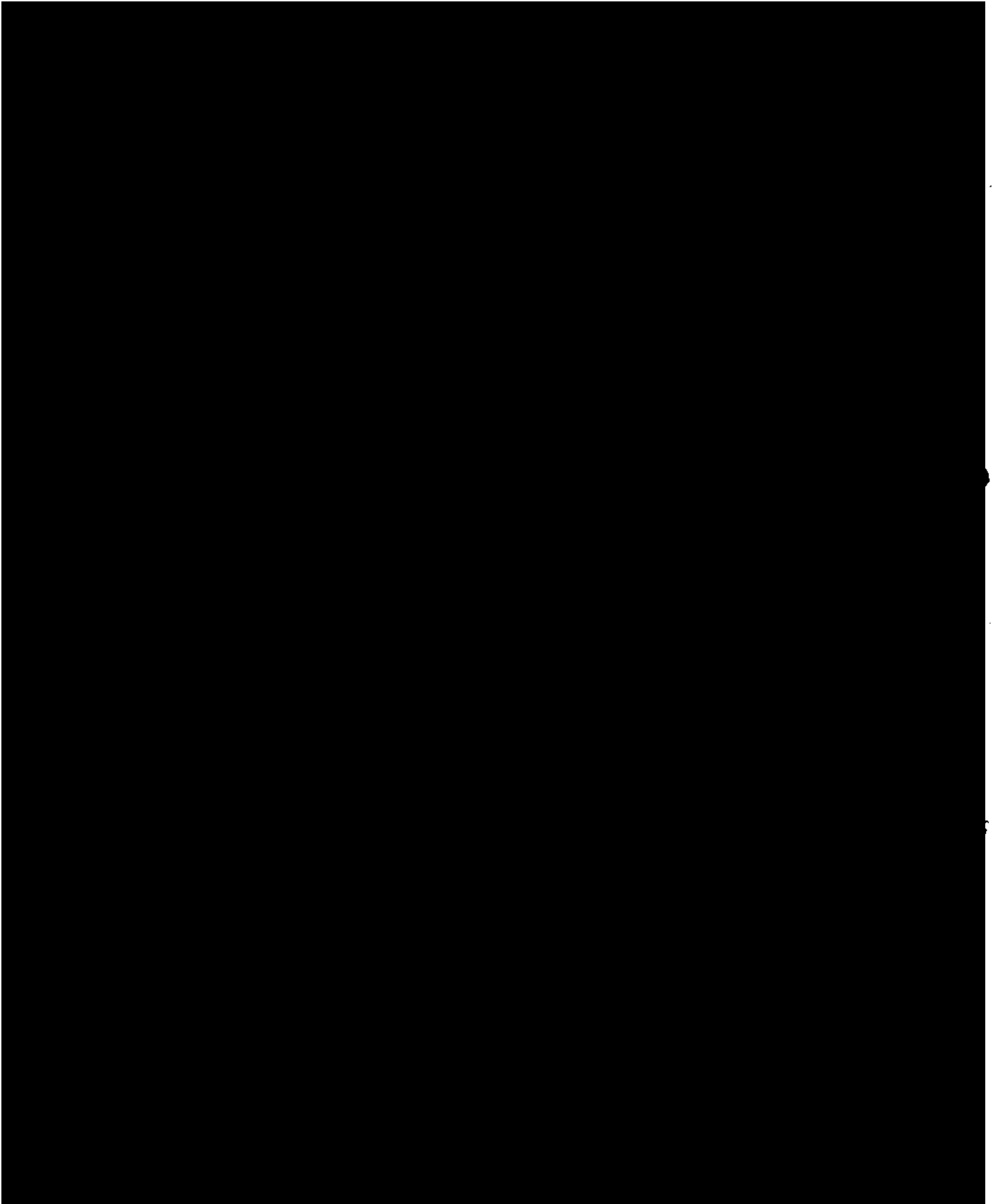
Chris Kaczmarek

05/20/03 09:40 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Amber Aranda
Subject: AF36

*Deliberative
Attorney-Client Communication
Attorney-Client Privilege*

Shanaz,





Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel
(202) 564-3909



Chris Kaczmarek

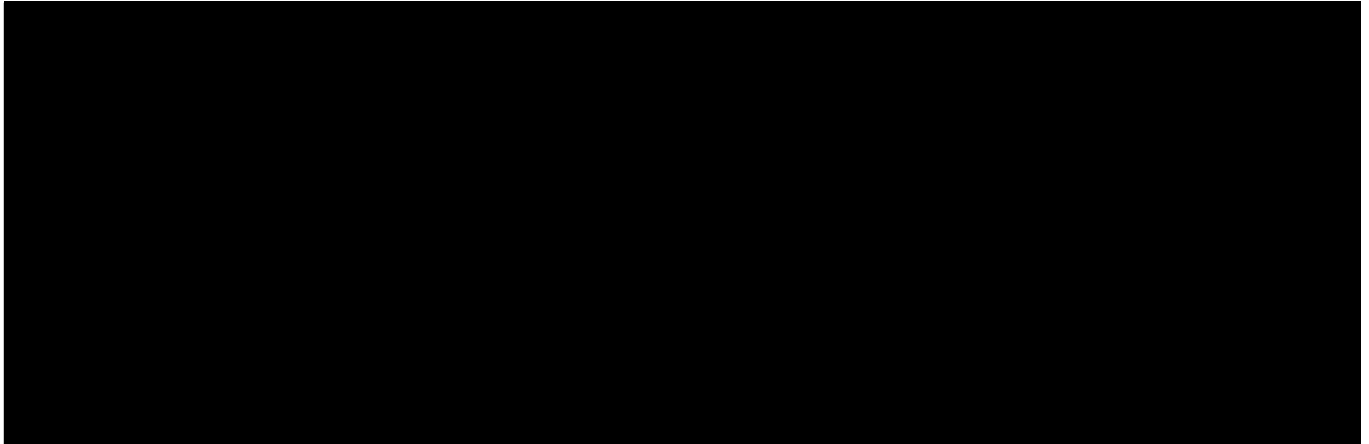
05/16/03 12:43 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA

cc:

Subject: AF36

Shanaz,





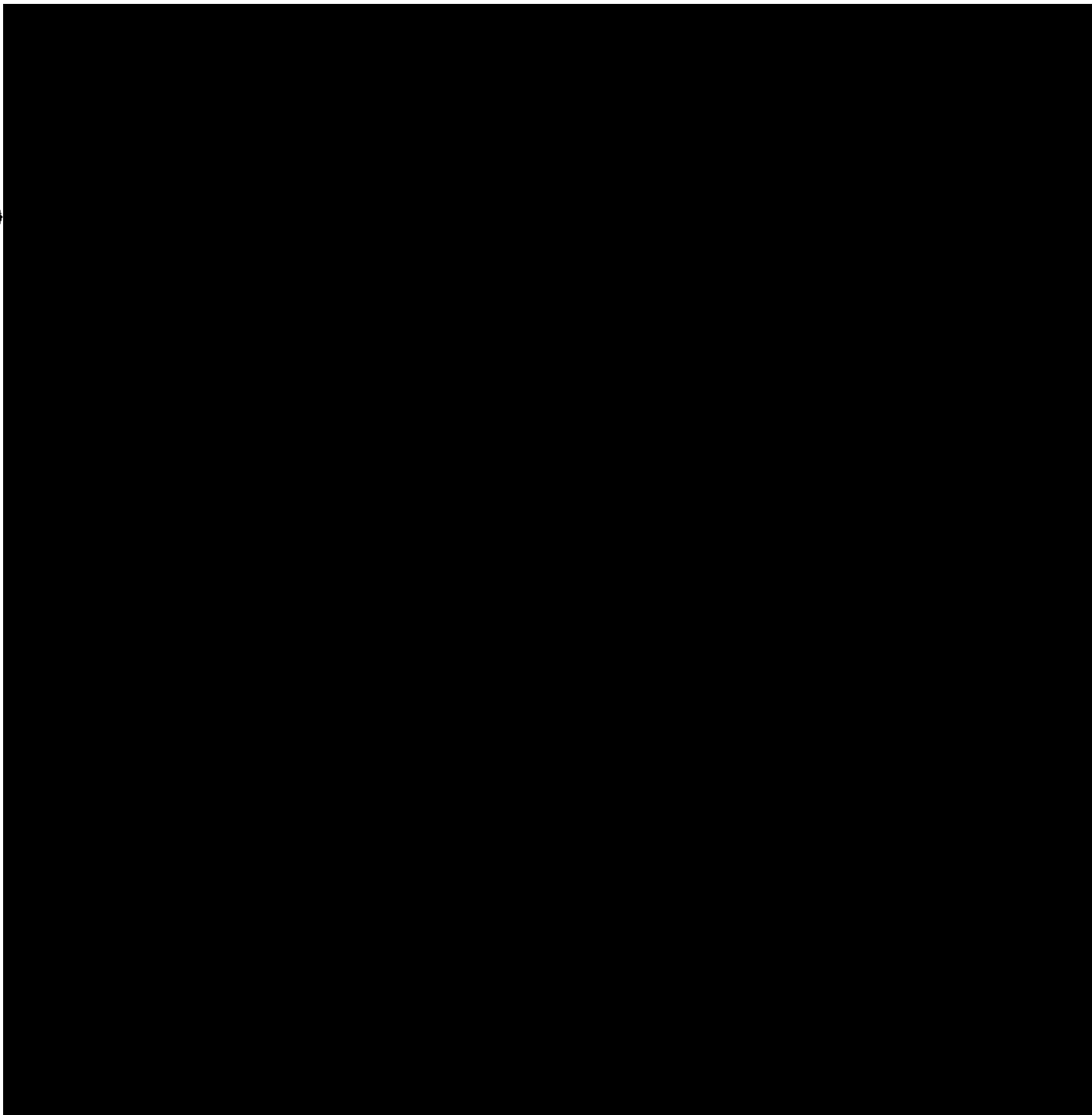
Chris Kaczmarek

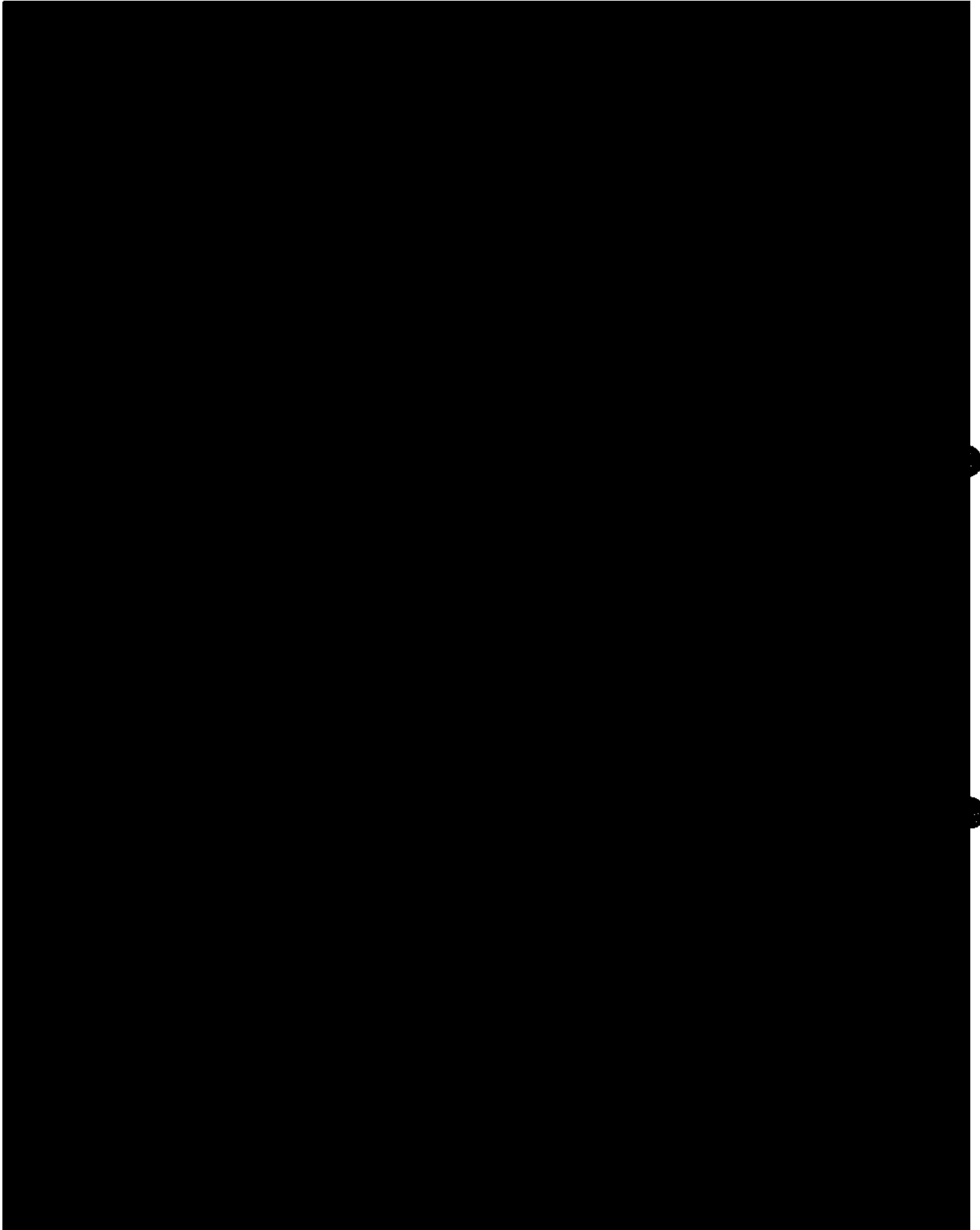
05/20/03 09:40 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Amber Aranda
Subject: AF36

*Deliberative
Attorney-Client Communication
Attorney-Client Privilege*

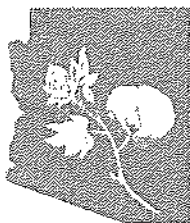
Shanaz,







Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel
(202) 564-3909



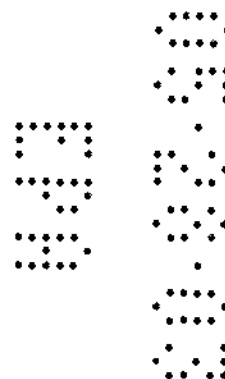
ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

Dennis Szuhay, Acting Chief
Microbial and Plant Incorporated Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 910, Crystal Mall 2
Arlington Virginia, 22202
(703) 308-8260

May 23, 2003

RE: Pending Section 3 Registration-*Aspergillus flavus* AF36
EPA Reg. No. 71693-R; Active Ingredient # 006546
Pending Pesticide Petition # 8E5001
RAL Shauaz Bacchus (703)308-8097



Dear Dennis:

This is in response to your letter dated May 22, 2003 (attached) notifying us about our active ingredient *Aspergillus flavus* AF36 eligibility for a conditional Section 3(c)7(C) registration on cotton in AZ and TX. We are hereby committing to provide the following data within the time frames you requested as shown below as conditions of registration:

I. Guidelines 151-10 through 151-16 (OPPTS Gdln 885.1300): Product Identity

Analyses of 5 batches is required at production and must include data relevant to certification of limits, detection, identification, enumeration and rejection limits of metabolites and potential human pathogens (bacterial and fungal) using routine quality control and assurance methods to be implemented for large scale production. Batch analysis must also include viability and storage stability data. All batches containing human pathogens above regulatory levels must be destroyed. A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36. Data to remove this condition of registration must be submitted within 2.5 years of the conditional registration. If at any time the formulation, manufacturing process or quality control methods change, you must submit appropriate relevant data to amend the conditional registration of this microbial active ingredient.

Our understanding of "enumeration and rejection limits of metabolites" is that we will continue to analyze for aflatoxin in the working culture by TLC in all batches as already described in MRID 44626101 which is prior to inoculating the wheat. We agree to do the analysis for aflatoxin as a post production analysis only as part of the five batch analysis, but there will not be any post production analysis for aflatoxin as part of the routine quality control procedure.

Similarly, our understanding of "A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36" means that we will continue to utilize vegetative compatibility grouping as a test prior to and after production. We agree to use a DNA based confirmatory method only on the 5 batch analysis, but not as part of the routine quality control procedure.

2. Efficacy data are required from a large scale field trial in TX to confirm the bridging of data from Arizona to Texas and to demonstrate that *Aspergillus flavus* AF36 reduces aflatoxin-producing strains of *Aspergillus flavus*

A table clarifying these data requirements is below. Through communication with Shanaz Bacchus, we understand that you already have the appropriate final draft label for stamping. We understand that further data may be required for different formulations and application methods and other use sites, on a case by case basis, if such amendments ensue during this conditional registration.

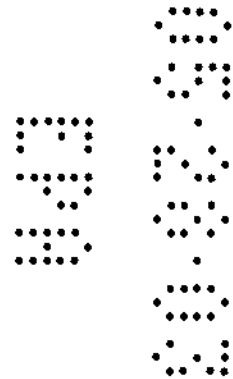
Data required as a condition of Registration of <i>Aspergillus flavus</i> AF36			
Guideline	Title of Study	Data Required	Due Date
885.1300 151B-12	Discussion of Formation of Unintentional Ingredients	Formation of unintentional ingredients, human pathogen and metabolite identification and quantification (including aflatoxin quantification).	During production of 5 batches or 2.5 years after conditional registration date.
*885.1400 151B-13	Analysis of Samples	5 batch analysis to include viability and storage stability data.	During production of 5 batches or 2.5 years after conditional registration date.
*885.1500 151B-15	Certification of limits	Standard data requirement for production batches.	During production of 5 batches or 2 years after conditional registration date.
Non-guideline: required for public health hazard	Efficacy/Product Performance	Efficacy/Product Performance data to demonstrate the reduction of toxigenic strains by <i>A. flavus</i> AF36 in Texas.	2.5 years after conditional registration date.

Sincerely,



Larry Antilla,
Staff Director
Arizona Cotton Research and Protection Council

CC: Shanaz Bacchus, BPPD, USEPA
Phil Hutton, BPPD, USEPA
Janet Andersen, BPPD, USEPA
Peter Cotty, USDA-ARS
Phil Wakelyn, National Cotton Council



ROUTING AND TRANSMIT

Date

6/24/03

TO: (Name, office symbol, room number, building, Agency/ Post)

Initials

Date

1. *Diana Hudson*
2. *Janet Andersen (sign)*
3. *Diana Hudson (DCN)*

4.

5.

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	<input checked="" type="checkbox"/> Signature
Coordination	Justify	

REMARKS

*Funds AF 36
Final rule
Please give me a copy.*

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/ Post)

Room No. — Bldg.

Shawn

Phone No.

308-8097

NSN 7540-00-935-5862
5041-103



OPTIONAL FORM 41 (Rev. 1-94)
Prescribed by GSA
UNICOR FPI - SST

TO: (Name, office symbol, room number, building, Agency/Post)		Initials	Date
1. <i>Shanez Bacchus</i> <i>7511C</i>			
2.			
3.			
4.			
5.			
<input type="checkbox"/>	Action	<input type="checkbox"/>	File
<input type="checkbox"/>	Approval	<input type="checkbox"/>	For Clearance
<input type="checkbox"/>	As Requested	<input type="checkbox"/>	For Correction
<input type="checkbox"/>	Circulate	<input type="checkbox"/>	For Your Information
<input type="checkbox"/>	Comment	<input checked="" type="checkbox"/>	Investigate
<input type="checkbox"/>	Coordination	<input type="checkbox"/>	Justify
REMARKS: Pesticide When the package has been completed, including the typesetting request form, please return this signed package to: Emily Glover, 7104T. Thanks. <i>OPP-2003-0138 = 03P-854</i>			
FROM: (Name, org, symbol, Agency/Post) Emily Glover OPPTS Federal Register Staff 7104T			
Room No.-Bldg. 6109J, ICC 6th Floor Connector, 12 th & Constitution Ave. NW		Phone No. 566-1595	

ACTION: R SCREEN: REQL USERID: SHUI

06/25/03 . 01:10:04 PM

*** REQUISITION ACCOUNTING LINE INQUIRY TABLE ***

KEY IS TRANS CODE, REQ NO, LINE NO

TRANS CODE: RQ

REQ NO: 0332JF3022

01- LINE NO: 001	BFY: 2003 2004	APPR: B	RPIO: 20	
BUDGET ORG: 32N00QB	PE: 40102C	LINE AMT:		1,853.00
COST ORG:	SITE/PROJ:	CLOSED AMT:		0.00
BOC: 2413	RPTG CATG:	OBLG AMT:		0.00
LAST CHG STATUS:	DESCRIPTION: FRL-7311-6 ASPERGILLUS FLAVUS			
02- LINE NO:	BFY:	APPR:	RPIO:	
BUDGET ORG:	PE:	LINE AMT:		
COST ORG:	SITE/PROJ:	CLOSED AMT:		
BOC:	RPTG CATG:	OBLG AMT:		
LAST CHG STATUS:	DESCRIPTION:			
03- LINE NO:	BFY:	APPR:	RPIO:	
BUDGET ORG:	PE:	LINE AMT:		
COST ORG:	SITE/PROJ:	CLOSED AMT:		
BOC:	RPTG CATG:	OBLG AMT:		
LAST CHG STATUS:	DESCRIPTION:			

02-*L009 HEADER CHANGE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

Memorandum

SUBJECT: Cost of Publishing Documents in the Federal Register

FROM: John A. Richards, Director, OPPTS Federal Register Staff (7104T)

TO: OPPTS Document Drafters

In view of the limited amount of money that will be available for publishing documents in the Federal Register in the current fiscal year, the OPPTS Federal Register Staff is cooperating with budget and program personnel by keeping you informed of printing costs.

This document when prepared with electronic encoding will bill as follows:

Document OPPTS No.: 03P-0854

Pages/columns: 17

Approximate cost: \$ 1,853

We are furnishing this information so that you will be better able to allocate your funds during the remainder of the fiscal year. Unless a deliberate decision is made to withhold this document from publication, it will be forwarded automatically for publication upon its receipt after signature by my office. A hold can be placed on actual publication by calling the Federal Register Staff on (566-1580) prior to signature, and providing alternate instructions.

For OPPTS FR Staff Use Only

Expedited (Check One)		Templated Documents				Shell Documents				Adj. Value
		Text Pages		Tables		Text Pages		Tables		
		Initial Text	Revised Text	Initial Text	Revised Text	Initial Text	Revised Text	Initial Text	Revised Text	
Yes	No									
	✓	17								



United States
Environmental Protection Agency
Washington, DC 20460

FEDERAL REGISTER TYPESETTING REQUEST

Requestor: Complete items 1, 2, T, S, 9, 10, 11, 12 and 13. Retain copy number 7 and submit the balance with manuscript copy to the Hq. Federal Register Office.
HQ Federal Register Office: Complete items 3, 4, 5 and 6. Retain copy number 6 and submit balance to Hq. Printing Management.

1. TITLE OPP-2003-0138 Aspergillus flavus A F 36: EXEMPTION FROM TOLERANCE

2. SUBMITTING ACTIVITY

3. ASSIGNED FRL NUMBER (include alpha & numeric characters for identification.)
7311-6

4. OPEN REQUISITION NUMBER

5. BILLING CODE
6560-50-S

6. FORWARDED TO GSA, NARS - SIGNATURE

DATE

7. NUMBER OF MANUSCRIPT PAGES

8. ESTIMATED NUMBER OF COLUMNS

9. ESTIMATED COST

17

\$ 1,853

10. SIGNATURE: (a) REQUESTING OFFICER

11. SIGNATURE: (a) FEDERAL REGISTER DESIGNEE

Janet L. Andersen, Ph.D., Director, BPPD

Pamela Landis

(b) DATE

(c) TELEPHONE NUMBER

703-308-8712

(b) DATE

(c) TELEPHONE NUMBER

6-25-03

703-308-7013

12. FUNDS ARE AVAILABLE

Pamela Landis

NAME OF FUNDS CERTIFYING OFFICER

S. Diana Hudson

SIGNATURE OF FUNDS CERTIFYING OFFICER

703-308-7013

PHONE NUMBER OF FUNDS CERTIFYING OFFICER

03P-854

Emily

This document was submitted with sgml tags and is eligible for the 35% typesetting discount.

13. Financial and Accounting Data

Line	QCH (Max 6)	Budget/FYs (Max 4)	Appropriation Code (Max 8)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)
1	JF3022	03 04	B	32N00QB	40102C	2413
2						
3						

SFO

27

(Max 2)

	Amount	(Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1	\$1,853.00	81853	00		
2					
3					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 22 2003

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

Dr. Michael Braverman
Interregional Research Project Number 4 (IR-4)
New Jersey Agricultural Experiment Station
Technology Center of New Jersey
681 U. S. Highway #1 South
North Brunswick, NJ 08902-3390

Dear Dr. Braverman:

Pending Section 3 Registration - *Aspergillus flavus* AF36
EPA Reg. No. 71693-R; Active ingredient # 006546
Pending Pesticide Petition # 8E5001

This letter is sent to you regarding the pending Section 3(c) registration action you filed on behalf of Mr. Larry Antilla, Arizona Cotton Research and Protection Council, 3721 East Weir Avenue, Phoenix, Arizona 85040-2933. The product above, *Aspergillus flavus* AF36, also referred to as AF36, will be acceptable for conditional registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), provided that you agree in writing that you will submit the data required within 2 to 2.5 years from the date of registration as discussed on page 4 of this letter.

The status of the data submissions in support of these guideline requirements for the subject registration, *Aspergillus flavus* AF36, containing the active ingredient *Aspergillus flavus* AF36 (ai #006540) is summarized below.

I. Health Effects Data

1. Guidelines 151-10 through 151-16 (OPPTS Gdtn 885.1300): Product Identity, Manufacturing Process and Quality Control

Product identity and manufacturing data support the conditional registration of *Aspergillus flavus* AF36. Starter cultures are monitored for aflatoxin production by standard thin layer chromatography (TLC) procedures and visualization via scanning fluorescence densitometry [MRID 44626101; BPPD Review, March 29, 1999]. Starter cultures are to be screened for human pathogens, metabolites and unintentional ingredients to assure quality control. The inert ingredient for the End-use Product, sterilized wheat seed, which serves as a matrix for the inoculant, is exempt from the requirement of a tolerance under 40 CFR 180.950(a) and is cleared for food use. These data are acceptable for this conditional registration. Analysis of 5 production batches is required within 2.5 years as discussed later in this letter.

2. a. Acute Oral Toxicity/Pathogenicity (OPPTS 885.3050; MRID 43972403)

No toxicity/infectivity was associated with *A. flavus* AF36 according to the evaluation of the acute oral study and the pesticide was classified Toxicity Category IV. No further data are required for this guideline for the use of AF36 on cotton in AZ and TX.

b. Acute Pulmonary Toxicity/Pathogenicity (OPPTS Harmonized Guideline 885.3150; MRIDs 45798101, 45798201, MRID 45739101)

No clinical signs that were considered to be due to the fungal active ingredient were observed in the test rats following intratracheal installation of *A. flavus* AF36. Clearance from organs, examined *post mortem*, demonstrated *A. flavus* AF36 was not toxic, infective, or pathogenic to rats (BPPD Review - April 02, 2003c). The study is ACCEPTABLE. On the basis of this study and the nature of the inert ingredients present, the pesticide was considered Toxicity Category III for acute pulmonary infectivity/toxicity effects. No further data are required for this guideline for the proposed use of AF36 on cotton in AZ and TX..

c. Acute inhalation (OPPTS Guideline 152-32)

The inert, sterilized wheat seeds, comprising more than 99% of this pesticidal product, acts as a matrix and nutrient source for the germinating AF36. Because colonized wheat seeds constitute more than 20% of the pesticide and contains non-respirable particles greater than 10 microns, an acute mammalian inhalation study is not required. In addition, based on the results obtained through the acute pulmonary toxicity/pathogenicity studies summarized immediately above, the Agency has determined that AF36, is considered not toxic, infective, or pathogenic to the rat pulmonary system.

d. Hypersensitivity Incidents (OPPTS Guideline 152-37; MRID 45739104)

No recorded or reported adverse hypersensitivity reaction to AF36 was reported by a state council or 6 companies during use for 3 or 6 years (MRID 45739104; BPPD Review - April 02, 2003d). A hypersensitivity study is not required, based on this report. However, to comply with the FIFRA requirements under Section 6(a)(2), you must report any incident of hypersensitivity associated with the use of this pesticide to the Agency.

e. Data Waiver Requests: Health Effects

The following Data Waiver Requests for Health Effects were granted on the basis of justifiable rationales submitted:

- (i) Acute Dermal Toxicity/Pathogenicity (OPPTS 885.3100)
- (ii) Primary Dermal Irritation (OPPTS 870.2500)
- (iii) Primary eye irritation (OPPTS 870.2400)
- (iv) Intravenous, Intracerebral, Intraperitoneal injection (OPPTS 885.3200)
- (v) Hypersensitivity study (40 CFR 152-36)
- (vi) Immune response (40 CFR 152-38)

Acceptable rationales, supporting these data waiver requests, included:

- (a) no toxicity/infectivity effects, and demonstrable clearance from organs examined post mortem as demonstrated in the acute oral study (MRID 43972403: BPPD Review - April 23, 1996);
- (b) following oral and pulmonary routes of exposure (BPPD Review - April 23, 1996; BPPD Review - April 02, 2003b), the immune system is still intact and able to process and clear the active ingredient;
- (c) hypersensitivity incidents were not reported from maximally exposed workers and researchers during the research and experimental phases associated with the use of the active ingredient, *A. flavus* AF36 (BPPD Review - April 02, 2003d);
- (d) non-occupational dermal and eye exposures, or exposures via any of the routes in (e)(i) thru (vi) above, are not likely to be above background levels because (a) spray drift is not expected due to the granular nature of the pesticide, and (b) treatment of agricultural sites, by aerial and ground application methods, without cultivation, is not likely to increase these exposures beyond normally occurring *A. flavus* levels. Based on the acceptable data waiver rationales, no further data are required for these guidelines for the proposed use of AF36 in AZ and TX.

II. Ecological Effects Data

The following data submissions were reviewed and found acceptable to the Agency for the proposed use of AF36 on cotton in AZ and TX:

b. Acute Pulmonary Toxicity/Pathogenicity (OPPTS Harmonized Guideline 885.3150; MRIDs 45798101, 45798201, MRID 45739101)

No clinical signs that were considered to be due to the fungal active ingredient were observed in the test rats following intratracheal installation of *A. flavus* AF36. Clearance from organs, examined *post mortem*, demonstrated *A. flavus* AF36 was not toxic, infective, or pathogenic to rats (BPPD Review - April 02, 2003c). The study is ACCEPTABLE. On the basis of this study and the nature of the inert ingredients present, the pesticide was considered Toxicity Category III for acute pulmonary infectivity/toxicity effects. No further data are required for this guideline for the proposed use of AF36 on cotton in AZ and TX..

c. Acute inhalation (OPPTS Guideline 152-32)

The inert, sterilized wheat seeds, comprising more than 99% of this pesticidal product, acts as a matrix and nutrient source for the germinating AF36. Because colonized wheat seeds constitute more than 20% of the pesticide and contains non-respirable particles greater than 10 microns, an acute mammalian inhalation study is not required. In addition, based on the results obtained through the acute pulmonary toxicity/pathogenicity studies summarized immediately above, the Agency has determined that AF36, is considered not toxic, infective, or pathogenic to the rat pulmonary system.

d. Hypersensitivity Incidents (OPPTS Guideline 152-37; MRID 45739104)

No recorded or reported adverse hypersensitivity reaction to AF36 was reported by a state council or 6 companies during use for 3 or 6 years [MRID 45739104; BPPD Review - April 02, 2003d]. A hypersensitivity study is not required, based on this report. However, to comply with the FIFRA requirements under Section 6(a)(2), you must report any incident of hypersensitivity associated with the use of this pesticide to the Agency.

e. Data Waiver Requests: Health Effects

The following Data Waiver Requests for Health Effects were granted on the basis of justifiable rationales submitted:

- (i) Acute Dermal Toxicity/Pathogenicity (OPPTS 885.3100)
- (ii) Primary Dermal Irritation (OPPTS 870.2500)
- (iii) Primary eye irritation (OPPTS 870.2400)
- (iv) Intravenous, Intracerebral, Intraperitoneal injection (OPPTS 885.3200)
- (v) Hypersensitivity study (40 CFR 152-36)
- (vi) Immune response (40 CFR 152-38)

Acceptable rationales, supporting these data waiver requests, included:

- (a) no toxicity/infectivity effects, and demonstrable clearance from organs examined post mortem as demonstrated in the acute oral study [MRID 43972403; BPPD Review - April 23, 1996];
- (b) following oral and pulmonary routes of exposure (BPPD Review - April 23, 1996; BPPD Review - April 02, 2003b), the immune system is still intact and able to process and clear the active ingredient;
- (c) hypersensitivity incidents were not reported from maximally exposed workers and researchers during the research and experimental phases associated with the use of the active ingredient, *A. flavus* AF36.[BPPD Review - April 02, 2003d];
- (d) non-occupational dermal and eye exposures, or exposures via any of the routes in (e)(i) thru (vi) above, are not likely to be above background levels because (a) spray drift is not expected due to the granular nature of the pesticide, and (b) treatment of agricultural sites, by aerial and ground application methods, without cultivation, is not likely to increase these exposures beyond normally occurring *A. flavus* levels. Based on the acceptable data waiver rationales, no further data are required for these guidelines for the proposed use of AF36 in AZ and TX.

II. Ecological Effects Data

The following data submissions were reviewed and found acceptable to the Agency for the proposed use of AF36 on cotton in AZ and TX:

a. Acute avian inhalation infectivity/pathogenicity (OPPTS 885.4100; MRID 45798102)

No toxic effects were observed in the avian inhalation study, following intratracheal instillation of AF36 in the bobwhite quail. No further data are required for this guideline for the proposed use of AF36 on cotton in AZ and TX.

b. Toxicity/Pathogenicity - Honeybees (MRID 45739102; OPPTS 885.4380)

The exposure and potential hazard of AF36 colonized-wheat seed to foraging honey bees (*Apis mellifera* L.) on blooming cotton was assessed for 30 days, following an aerial application at label rates. On the basis of this study, AF36 applied once at 10 lbs EP/acre is not considered hazardous to honey bees. No further data are required for this guideline for the proposed use of AF36 on cotton in AZ and TX.

c. Efficacy/Product Performance (MRIDs 45307201, 45307202 OPPTS 885.5000)

Results of multiple year soil and air population monitoring studies indicate that the number of *A. flavus* conidia increase within a few days of application as is expected of the germinating microbial pesticide. The results also suggest that AF36 applications do not significantly increase the overall quantity of *Aspergillus flavus* at cotton crop maturity, nor in the soil one year after application. These data are acceptable for product performance of AF36 for the proposed uses on cotton in Arizona (AZ). Further data, to confirm the bridging of data from AZ to Texas (TX) are required to demonstrate product performance in TX.

d. Data Waiver Requests: Ecological Effects

The following Data Waiver Requests for Ecological Effects were granted on the basis of justifiable rationales submitted to the Agency:

(i) Acute avian oral toxicity/pathogenicity (Guideline 154A-16, OPPTS 885.4050)

The data requirement was waived based on no toxic effects observed in the avian inhalation study as noted above. No further data are required for this guideline for the proposed use of AF36.

(ii) Freshwater Fish toxicity/pathogenicity (OPPTS 885.4240)

(iii) Estuarine and Marine Animal testing (OPPTS 885.4280)

(iv) Freshwater Aquatic Invertebrate Toxicity/Pathogenicity (OPPTS 885.4240)

(v) Non-target Plant (OPPTS 885.4300)

(vi) Non-target insect (OPPTS 885.4340)

Data requirements for the ecological guidelines listed in 1-5 were also waived on rationales of exposure of non-target organisms not being above current background levels of *A. flavus* strains.

III. Conditions of Registration

On the basis of the evaluations above, the active ingredient *Aspergillus flavus* AF36 is eligible for a conditional Section 3(c)(7)(C) registration for use on cotton in AZ and TX. You must commit in writing to provide the following data within the time frames shown below as conditions of registration:

1. Guidelines 151-10 through 151-16 (OPPTS GdIn 885.1300): Product Identity

Analysis of 5 batches is required at production and must include data relevant to certification of limits, detection, identification, enumeration and rejection limits of metabolites and potential human pathogens (bacterial and fungal) using routine quality control and assurance methods to be implemented for large scale production. Batch analysis must also include viability and storage stability data. All batches containing human pathogens above regulatory levels must be destroyed. A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36. Data to remove this condition of registration must be submitted within 2.5 years of the conditional registration. If at any time the formulation, manufacturing process or quality control methods change, you must submit appropriate relevant data to amend the conditional registration of this microbial active ingredient.

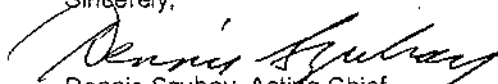
2. Efficacy data are required from a large scale field trial in TX to confirm the bridging of data from Arizona to Texas and to demonstrate that *Aspergillus flavus* AF36 reduces aflatoxin-producing strains of *Aspergillus flavus*.

Page 4 of 5

A table to clarify these data requirements is enclosed and will be included in the Biopesticide Registration Action Document. The "Notice of Registration" will be issued when you have agreed in writing to the conditions stated in this letter and provide the appropriate final draft label for stamping. Further data may be required for different formulations and application methods and other use sites, on a case by case basis, if such amendments ensue during this conditional registration. This letter does not constitute registration, and the product may not be lawfully marketed until it is registered.

If you have any questions, do not hesitate to call Shanaz Bacchus at 703-308-8097.

Sincerely,



Dennis Szuhay, Acting Chief
Microbial and Plant Incorporated Pesticides Branch
Biopesticides and Pollution
Prevention Division


encl.

Page 4 of 5

A table to clarify these data requirements is enclosed and will be included in the Biopesticide Registration Action Document. The "Notice of Registration" will be issued when you have agreed in writing to the conditions stated in this letter and provide the appropriate final draft label for stamping. Further data may be required for different formulations and application methods and other use sites, on a case by case basis, if such amendments ensue during this conditional registration. This letter does not constitute registration, and the product may not be lawfully marketed until it is registered.

If you have any questions, do not hesitate to call Shanaz Bacchus at 703-308-8097.

Sincerely,



Dennis Szuhay, Acting Chief
Microbial and Plant Incorporated Pesticides Branch
Biopesticides and Pollution
Prevention Division

encl.

Attachment 1

Page 1 of 1

Data required as a condition of Registration of *Aspergillus flavus* AF36

Guideline	Title of Study	Data required	Date due
885.1300 151B-12	Discussion of Formation of Unintentional Ingredients	Formation of unintentional ingredients, human pathogen and metabolite identification and quantification (including aflatoxin quantification).	During production of 5 batches or 2.5 years after conditional registration date.
*885.1400 151B-13	Analysis of Samples	5 batch analysis to include viability and storage stability data.	During production of 5 batches or 2.5 years after conditional registration date.
*885.1500 151B-15	Certification of limits	Standard data requirement for production batches.	During production of 5 batches or 2 years after conditional registration date.
Non-guideline: required for public health hazard	Efficacy/Product Performance	Efficacy/Product Performance data to demonstrate the reduction of toxigenic strains by <i>A. flavus</i> AF36 in Texas.	2.5 years after conditional registration date.

Post-It [®] Fax Note	7671	Date	# of pages 5
To Mike Braverman		From Shanaaz Parthasarathy	
Co./Dept. USDA/IR-4		Co. USDA/OP/PPD	
Phone # 732-932-9575 x610		Phone # 703 368-8097	
Fax # 732-932-8481		Fax # 703 368-7026	

United States Environmental Protection Agency

MAY 22 2003

Dr. Michael Braverman
Interregional Research Project Number 4 (IR-4)
New Jersey Agricultural Experiment Station
Technology Center of New Jersey
681 U. S. Highway #1 South
North Brunswick, NJ 08902-3390

Dear Dr. Braverman:

Pending Section 3 Registration - *Aspergillus flavus* AF36
EPA Reg. No. 71693-R; Active ingredient # 006546
Pending Pesticide Petition # 8E5001

This letter is sent to you regarding the pending Section 3(c) registration action you filed on behalf of Mr. Larry Anttila, Arizona Cotton Research and Protection Council, 3721 East Weir Avenue, Phoenix, Arizona 85040-2933. The product above, *Aspergillus flavus* AF36, also referred to as AF36, will be acceptable for conditional registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), provided that you agree in writing that you will submit the data required within 2 to 2.5 years from the date of registration as discussed on page 4 of this letter.

The status of the data submissions in support of these guideline requirements for the subject registration, *Aspergillus flavus* AF36, containing the active ingredient *Aspergillus flavus* AF36 (a) #006540) is summarized below.

I. Health Effects Data

1. Guidelines 151-10 through 151-16 (OPPTS Gdn 885.1300): Product Identity, Manufacturing Process and Quality Control

Product identity and manufacturing data support the conditional registration of *Aspergillus flavus* AF36. Starter cultures are monitored for aflatoxin production by standard thin layer chromatography (tlc) procedures and visualization via scanning fluorescence densitometry [MRID 4462610 t; BPPD Review, March 29, 1999]. Starter cultures are to be screened for human pathogens, metabolites and unintentional ingredients to assure quality control. The inert ingredient for the End-use Product, sterilized wheat seed, which serves as a matrix for the inoculant, is exempt from the requirement of a tolerance under 40 CFR 180.950(a) and is cleared for food use. These data are acceptable for this conditional registration. Analysis of 5 production batches is required within 2.5 years as discussed later in this letter.

2. a. Acute Oral Toxicity/Pathogenicity (OPPTS 885.3050; MRID 43972403)

No toxicity/infectivity was associated with *A. flavus* AF36 according to the evaluation of the acute oral study and the pesticide was classified Toxicity Category IV. No further data are required for this guideline for the use of AF36 on cotton in AZ and TX.

SB:7511C:05222003:7033088097:006456:71693R:8E5001

CONCURRENCES							
SYMBOL	7511C	7511C	7511C	7511C			
SURNAME	B. HILLIS	J. KOUEN	J. KOUEN	S. ZAHAY			
DATE	5/22/03	5-22-03	5-22-03	5-22-03			

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY 182

b. Acute Pulmonary Toxicity/Pathogenicity (OPPTS Harmonized Guideline 885.3150; MRIDs 45798101, 45798201, MRID 45739101)

No clinical signs that were considered to be due to the fungal active ingredient were observed in the test rats following intratracheal installation of *A. flavus* AF36. Clearance from organs, examined *post mortem*, demonstrated *A. flavus* AF36 was not toxic, infective, or pathogenic to rats [BPPD Review - April 02, 2003c]. The study is ACCEPTABLE. On the basis of this study and the nature of the inert ingredients present, the pesticide was considered Toxicity Category III for acute pulmonary infectivity/toxicity effects. No further data are required for this guideline for the proposed use of AF36 on cotton in AZ and TX..

c. Acute inhalation (OPPTS Guideline 152-32)

The inert, sterilized wheat seeds, comprising more than 99% of this pesticidal product, acts as a matrix and nutrient source for the germinating AF36. Because colonized wheat seeds constitute more than 20% of the pesticide and contains non-respirable particles greater than 10 microns, an acute mammalian inhalation study is not required. In addition, based on the results obtained through the acute pulmonary toxicity/pathogenicity studies summarized immediately above, the Agency has determined that AF36, is considered not toxic, infective, or pathogenic to the rat pulmonary system.

d. Hypersensitivity Incidents (OPPTS Guideline 152-37; MRID 45739104)

No recorded or reported adverse hypersensitivity reaction to AF36 was reported by a state council or 6 companies during use for 3 or 6 years [MRID 45739104: BPPD Review - April 02, 2003d]. A hypersensitivity study is not required, based on this report. However, to comply with the FIFRA requirements under Section 6(a)(2), you must report any incident of hypersensitivity associated with the use of this pesticide to the Agency.

e. Data Waiver Requests: Health Effects

The following Data Waiver Requests for Health Effects were granted on the basis of justifiable rationales submitted:

- (i) Acute Dermal Toxicity/Pathogenicity (OPPTS 885.3100)
- (ii) Primary Dermal Irritation (OPPTS 870.2500)
- (iii) Primary eye irritation (OPPTS 870.2400)
- (iv) Intravenous, Intracerebral, Intraperitoneal injection (OPPTS 885.3200)
- (v) Hypersensitivity study (40 CFR 152-36)
- (vi) Immune response (40 CFR 152-38)

Acceptable rationales, supporting these data waiver requests, included:

- (a) no toxicity/infectivity effects, and demonstrable clearance from organs examined post mortem as demonstrated in the acute oral study [MRID 43972403: BPPD Review - April 23, 1996];
- (b) following oral and pulmonary routes of exposure [BPPD Review - April 23, 1996; BPPD Review - April 02, 2003b], the immune system is still intact and able to process and clear the active ingredient;
- (c) hypersensitivity incidents were not reported from maximally exposed workers and researchers during the research and experimental phases associated with the use of the active ingredient, *A. flavus* AF36 [BPPD Review - April 02, 2003d];
- (d) non-occupational dermal and eye exposures, or exposures via any of the routes in (e)(i) thru (vi) above, are not likely to be above background levels because (a) spray drift is not expected due to the granular nature of the pesticide, and (b) treatment of agricultural sites, by aerial and ground application methods, without cultivation, is not likely to increase these exposures beyond normally occurring *A. flavus* levels. Based on the acceptable data waiver rationales, no further data are required for these guidelines for the proposed use of AF36 in AZ and TX.

II. Ecological Effects Data

The following data submissions were reviewed and found acceptable to the Agency for the proposed use of AF36 on cotton in AZ and TX:

a. Acute avian inhalation infectivity/pathogenicity (OPPTS 885.4100; MRID 45798102)

No toxic effects were observed in the avian inhalation study, following intratracheal instillation of AF36 in the bobwhite quail. No further data are required for this guideline for the proposed use of AF36 on cotton in AZ and TX.

b. Toxicity/Pathogenicity - Honeybees (MRID 45739102; OPPTS 885.4380)

The exposure and potential hazard of AF36 colonized-wheat seed to foraging honey bees (*Apis mellifera* L.) on blooming cotton was assessed for 30 days, following an aerial application at label rates. On the basis of this study, AF36 applied once at 10 lbs EP/acre is not considered hazardous to honey bees. No further data are required for this guideline for the proposed use of AF36 on cotton in AZ and TX.

c. Efficacy/Product Performance (MRIDs 45307201, 45307202 OPPTS 885.5000)

Results of multiple year soil and air population monitoring studies indicate that the number of *A. flavus* conidia increase within a few days of application as is expected of the germinating microbial pesticide. The results also suggest that AF36 applications do not significantly increase the overall quantity of *Aspergillus flavus* at cotton crop maturity, nor in the soil one year after application. These data are acceptable for product performance of AF36 for the proposed uses on cotton in Arizona (AZ). Further data, to confirm the bridging of data from AZ to Texas (TX) are required to demonstrate product performance in TX.

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The following Data Waiver Requests for Ecological Effects were granted on the basis of justifiable rationales submitted to the Agency:

(i) Acute avian oral toxicity/pathogenicity (Guideline 154A-16, OPPTS 885.4050)

The data requirement was waived based on no toxic effects observed in the avian inhalation study as noted above. No further data are required for this guideline for the proposed use of AF36.

(ii) Freshwater Fish toxicity/pathogenicity (OPPTS 885.4240)

(iii) Estuarine and Marine Animal testing (OPPTS 885.4280)

(iv) Freshwater Aquatic Invertebrate Toxicity/Pathogenicity (OPPTS 885.4240)

(v) Non-target Plant (OPPTS 885.4300)

(vi) Non-target insect (OPPTS 885.4340)

Data requirements for the ecological guidelines listed in 1-5 were also waived on rationales of exposure of non-target organisms not being above current background levels of *A. flavus* strains.

III. Conditions of Registration

On the basis of the evaluations above, the active ingredient *Aspergillus flavus* AF36 is eligible for a conditional Section 3(c)7(C) registration for use on cotton in AZ and TX. You must commit in writing to provide the following data within the time frames shown below as conditions of registration:

1. Guidelines 151-10 through 151-16 (OPPTS Gdn 885.1300): Product Identity

Analysis of 5 batches is required at production and must include data relevant to certification of limits, detection, identification, enumeration and rejection limits of metabolites and potential human pathogens (bacterial and fungal) using routine quality control and assurance methods to be implemented for large scale production. Batch analysis must also include viability and storage stability data. All batches containing human pathogens above regulatory levels must be destroyed. A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36. Data to remove this condition of registration must be submitted within 2.5 years of the conditional registration. If at any time the formulation, manufacturing process or quality control methods change, you must submit appropriate relevant data to amend the conditional registration of this microbial active ingredient.

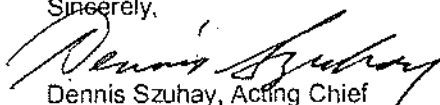
2. Efficacy data are required from a large scale field trial in TX to confirm the bridging of data from Arizona to Texas and to demonstrate that *Aspergillus flavus* AF36 reduces aflatoxin-producing strains of *Aspergillus flavus*

Page 4 of 5

A table to clarify these data requirements is enclosed and will be included in the Biopesticide Registration Action Document. The "Notice of Registration" will be issued when you have agreed in writing to the conditions stated in this letter and provide the appropriate final draft label for stamping. Further data may be required for different formulations and application methods and other use sites, on a case by case basis, if such amendments ensue during this conditional registration. This letter does not constitute registration, and the product may not be lawfully marketed until it is registered.

If you have any questions, do not hesitate to call Shanaz Bacchus at 703-308-8097.

Sincerely,



Dennis Szuhay, Acting Chief
Microbial and Plant Incorporated Pesticides Branch
Biopesticides and Pollution
Prevention Division

encl.

Data required as a condition of Registration of *Aspergillus flavus* AF36

Guideline	Title of Study	Data required	Date due
885.1300 t51B-12	Discussion of Formation of Unintentional Ingredients	Formation of unintentional ingredients, human pathogen and metabolite identification and quantification (including aflatoxin quantification).	During production of 5 batches or 2.5 years after conditional registration date.
*885.1400 151B-13	Analysis of Samples	5 batch analysis to include viability and storage stability data.	During production of 5 batches or 2.5 years after conditional registration date.
*885.1500 151B-15	Certification of limits	Standard data requirement for production batches.	During production of 5 batches or 2 years after conditional registration date.
Non-guideline: required for public health hazard	Efficacy/Product Performance	Efficacy/Product Performance data to demonstrate the reduction of toxigenic strains by <i>A. flavus</i> AF36 in Texas.	2.5 years after conditional registration date.

ROUTING & TRANSMITTAL SLIP

May 22, 2003

TO:	Name, office symbol, room number, building, Agency/Post	Initials	Date
1.	John Kough	JK	5-22
2.	Jim Downing	JD	5-22
3.	Dennis Szulay	DS	5-22
4.	Gail Tomimatsu		
5.			

MAY 22 2003

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify	X	Initials/Concurrence

MAY 22 2003

REMARKS

1. 71693-R
Aspergillus flavus AF36 Pending Acceptance Letter

FROM: (Name, org. symbol, Agency/Post)	Room No.-Bldg. CM2/910W38
	Phone No. 703-308-8097

Shamaz Bacchus

United States Environmental Protection Agency

CONCURRENCES

SYMBOL ▶	7511C							
SURNAME *								
DATE ▶								

Attached You Will Find an Updated Index for Your Docket:

Docket # <i>OPP-2003-0048</i>	Date Index Sent: APR - 9 2003
-------------------------------	-------------------------------

TO VIEW THE CONTENTS OF YOUR DOCKET and DOWNLOAD ANY COMMENTS RECEIVED, LOG ONTO EDOCKET AT: intranet.epa.gov/edocket.
Do a "Quick Search" for docket -*OPP-2003-0048*

OPP-2003-0048 Docket Index

Legacy Identifier: OPP-2003-0020

Title: Pesticide Product; Registration Application

Displaying 1- 13 of 13 Documents Found

Document ID	Date	Type	Title
OPP-2003-0048-0001	03-12-2003	Federal Register	Pesticide Product; Registration Application
OPP-2003-0048-0002	05-26-1999	Support-Background	Aspergillus Flavus Af36; Pesticide Tolerance Exemption
OPP-2003-0048-0003	05-23-2001	Support-Background	Aspergillus Flavus Af36; Extension of Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0048-0004	07-17-2002	Support-Background	Aspergillus Flavus Af36; Amendment, Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0048-0005	12-23-2002	Support-Background	Aspergillus Flavus AF36 ai#006456 Pending Section 3 Registration Number 71693-R, Petition 8E5001
OPP-2003-0048-0006	02-14-2003	Support-Background	Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0048-0007	03-26-2003	Public Comment	Comments from the Chandler Ginning Co. Re: Pesticide Product; Registration Application
OPP-2003-0048-0008	03-26-2003	Public Comment	Comments from the Farmer's Gin, Inc. Re: Pesticide Product; Registration Application
OPP-2003-0048-0009	03-27-2003	Public Comment	Comments from the Anderson Clayton Corp. Re: Pesticide Product; Registration Application
OPP-2003-0048-0010	04-04-2003	Public Comment	Comments from the Grower's Mohawk Gin, Inc. Re: Pesticide Product; Registration Application
OPP-2003-0048-0011	04-08-2003	Public Comment	Comments from the Texas A&M University Re: Pesticide Product; Registration Application
OPP-2003-0048-0012	03-21-2003	Public Comment	Comments from the Arizona Department of Agriculture Re: Pesticide Product; Registration Application
OPP-2003-0048-0013	03-20-2003	Public Comment	Comments from the National Cotton Council Re: Pesticide Product; Registration Application

2003-0020

(1P)

2003

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A TUMBLING T RANCHES
14929 W. Broadway Rd.
GOODYEAR, AZ 85338
Office (623)932-1834 Fax (623)932-3170
ATTRCH@aol.com

Public Information & Records Integrity Branch (7502C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW, Washington, DC 20460-000
Attention: Docket ID #OPP-2-3-0020

March 7, 2003

To Whom It May Concern:

This letter is my written comment on the application for an exemption from a tolerance and for registration of *Aspergillus flavus* AF36 for the prevention of aflatoxin contamination of cottonseed in Arizona.

I am a cotton farmer and the president of Farmers Gin, Inc. Historically, more than 50 percent of the cottonseed produced at our gin has tested higher than 20 ppb of aflatoxin. The majority of our 12,000 ton annual production goes to the dairy feed market. I estimate our losses at more than \$100,000 per year due to the higher levels.

High levels of aflatoxin are a serious problem in Arizona. The high levels reduced the value of the seed and place the seller at risk legally if subsequent tests show higher levels of contamination than that certified at the time of the sale. Several lawsuits and state regulatory administrative actions have occurred in recent years pitting dairymen and regulators against seed brokers, gins and cotton farmers.


There are no products currently on the market that will reduce or prevent aflatoxin contamination in any crop. There are also no cultural practices or biological controls that help reduce the levels.

The registration of *Aspergillus flavus* AF36 will be the first product available for reducing aflatoxin contamination of cottonseed. This product is needed by the industry in Arizona and in Texas as well.

I am pleased to hear that the product is not a synthetic chemical, but a naturally occurring strain of *Aspergillus* that does not produce aflatoxin and replaces the strains that do.

I strongly support the registration of AF36.

Sincerely,


F. Ronald Rayner
President
Farmers Gin, Inc.

MMS
55805
2003-
0020
0048

Anderson Clayton Corp.

2226 W. NORTHERN AVE., SUITE C201 • PHOENIX, AZ 85021

PHONE (602) 841-2111 • FAX (602) 841-2444

March 6, 2003

March 12 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Avenue NW
Washington DC 20460

pesticide 3/6/03

Attention: Docket ID Number OPP-2-3-0020

To Whom It May Concern:

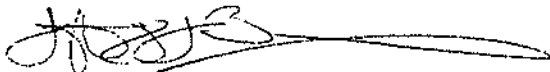
The Anderson Clayton Corporation conducts extensive cottonseed ginning and sales operations in Arizona where aflatoxin contamination has plagued growers for more than 30 years. This contamination has resulted in lost revenue and profit to Anderson Clayton, its raw material suppliers (cotton producers) and cottonseed feeders (primarily dairies) and cottonseed products consumers (again, primarily dairy, but other feed consumers as well).

The extraordinary fluctuations of aflatoxin contamination have resulted in losses for Arizona cotton producers in the millions of dollars.

It is our experience that no products are approved or even currently exist for treatment of any crop to prevent aflatoxin contamination in the field. *Aspergillus flavus* AF36, a biological control using no synthetic chemicals, is the first product available for reducing such contamination in cottonseed.

As a company that has directly and indirectly been affected by aflatoxin contamination of cottonseed, we have long tracked and supported the USDA ARS work conducted by Dr. Peter Cotty on aflatoxin in cottonseed and other agricultural commodities. Having seen first hand the negative financial exposure and impact aflatoxin contamination can have on our customers as well as our company, we strongly urge registration of *Aspergillus flavus* AF36 on cotton in Arizona and Texas.

Sincerely,



Jeffery J. Ballentine
V. P. Arizona Operations



Texas Agricultural Experiment Station

THE TEXAS A&M UNIVERSITY SYSTEM

10345 Agnes St.
Corpus Christi, TX 78406-1412
Phone: 361/265-9201 Fax: 361/265-9434
Web: <http://ccag.tamu.edu>

Agricultural Research and Extension Center at Corpus Christi

March 3, 2003

(1P)

Public Information and Records Integrity Branch
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460-000

Postmark 3/3/03

Attention: Docket ID Number OPP-2003-0020

This letter is in support of the application for Establishment of an Exemption from a Tolerance for the Microbial Pesticide *Aspergillus flavus* AF36 under Docket ID Number OPP-2003-0020. My comments relate to the registration of *Aspergillus flavus* AF36 as a microbial pesticide for the management of aflatoxin contamination in cottonseed.

We have serious problems with aflatoxin contamination of cottonseed in the gulf coast region of Texas causing millions of dollars in losses annually from sales and uses of cottonseed products in ruminant animal feeding. Serious problems also occur in cottonseed in other parts of Texas and in Arizona. Currently there are no alternatives to *Aspergillus flavus* for preventing aflatoxin contamination in cottonseed. Since there are no products currently available for preventing aflatoxin contamination in cottonseed or on any other crop, *Aspergillus flavus* AF36 is a product needed by the cotton industry in Texas and Arizona. We hope to have the opportunity to use *Aspergillus flavus* AF36 in developing effective control mechanisms to prevent aflatoxin contamination in cotton crops for our producers, the single most economically important crop produced in the lower gulf coast of Texas.

Thank you for consideration of this request.

Sincerely,

Bobby R. Eddleman, Ph.D.
Resident Director of Research
Texas Agricultural Experiment Station
Texas A&M University Agricultural
Research & Extension Center
10345 Agnes St.
Corpus Christi, TX. 78406

181



Texas Cooperative

EXTENSION

The Texas A&M University System

348 Soil and Crop Sciences • College Station, Texas 77843-2474 • (979) 845-2425 • FAX (979) 845-0604

OPP03-0020-0010

JP

March 7, 2003

10 2003

past march 3/11/03

Public Information and Records Integrity Branch (7502C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-000

RE: Docket ID Number OPP-2003-0020

This letter provides my support for establishment of an exemption from a tolerance for the microbial pesticide *Aspergillus flavus* AF36. AF36 is the first and only biological control method for eliminating aflatoxin contamination from cottonseed, and I strongly support the exemption.

Texas annually harvests between four and five million bales of cotton. Due to environmental conditions, several production regions face perennial problems from aflatoxin contaminated cottonseed. These regions include central Texas (Blackland Prairie and Bottomlands) which produces about 230,000 bales, the south Texas region (Upper Gulf Coast and Coastal Bend) which generates over 700,000 bales, and the Rio Grande Valley area which generates over 200,000 bales. Together these areas support the production of over 1.1 million bales.

According to information provided by the "Office of the State Chemist", cottonseed from these three regions will generally test positive for aflatoxin, and between 15 to 80% of the cottonseed will exceed 20 ppb. As an example, in 1997 and 1998 over 80% of the cottonseed from these regions tested greater than 20 ppb, and in 2001 less than 15% exceeded 20 ppb. When aflatoxin levels in cottonseed exceed the 20 ppb limit, the value of the seed is severely discounted (in most cases by greater than 50%), translating into several million dollars lost to producers and the cottonseed industry. Moreover, due to extremely low prices for cotton lint in current and near-future markets, any discounts in cottonseed value further reduces profitability at the farm level.

Presently, there are no known means of reducing/eliminating aflatoxin contamination on any crop. The use of atoxigenic strains of *Aspergillus flavus* have proven to be very effective in combating aflatoxin problems in Arizona. Considerable cumulative acres have been treated in Arizona with

no reported adverse effects. Multi-year air sampling studies have demonstrated that the atoxigenic strain AF36 has displaced the aflatoxin producing strains with no increase in total fungus in the environment.

Recent research conducted in the Coastal Bend region of Texas in 2000, 2001 and 2002 with the AF36 strain has also been very successful. However, these studies were limited to small acreages. Consequently, it is critical to the future success of the project to expand this effort and to establish a permanent exemption from tolerance for residues of *Aspergillus flavus* AF36.

Based on previous research in Arizona and Texas, and the success of the area-wide program in Arizona, the granting of this permanent exemption for AF36 will serve as a major step in reducing aflatoxin problems in Texas cottonseed. I strongly support the exemption for AF36 and urge the EPA to grant its approval.

Respectfully,



Robert G. Lemon
Associate Professor
and Extension Agronomist – Cotton
Department of Soil and Crop Sciences
Texas A&M University
College Station, Texas 77843-2474
r-lemon@tamu.edu

cc: Dr. Travis Müller
Dr. Mark Hussey
Dr. Peter Cotty
Dr. James Supak
Mr. Jeff Nunley



South Texas Cotton and Grain Association, Inc.

P.O. Box 4881 • Victoria, Texas 77903-4881 • Telephone: (361) 575-0631 • Fax: (361) 572-0960

March 13, 2003

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

MAR 19 2003

Received 3/13/03

RE: Docket ID Number OPP-2003-0020

South Texas Cotton and Grain Association submits these comments to strongly support the application for Establishment of an Exemption from a Tolerance for the Microbial Pesticide *Aspergillus flavus* AF36.

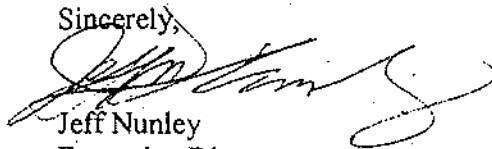
South Texas Cotton and Grain Association is a trade association representing producer members who farm cotton and grain crops in the 33 counties in the Coastal Bend of South Texas. Cotton is a primary crop for our producers and cottonseed is a valuable byproduct of cotton production.

Aflatoxin is a perennial problem for farmers in South Texas and contamination of cottonseed costs producers millions of dollars each year in lost of value. Work done in Arizona has shown that applying atoxigenic strain AF36, which occurs naturally in fields, is effective in reducing the amount of aflatoxin in cottonseed by displacing toxin producing strains (especially the S-strain of *Aspergillus flavus*) without increasing the total amount of fungus in the environment.

Texas is similar to Arizona in that the atoxigenic strain AF36 occurs naturally in South Texas fields. Texas is also similar to Arizona in that the S-strain of *Aspergillus flavus* is the primary cause of aflatoxin contamination in cottonseed. Experiments in Texas using very small test plots have shown that applying *Aspergillus flavus* AF36 is effective in reducing the level of the S-strain.

Presently, there are no alternative methods available to producers to reduce aflatoxin producing fungi in cotton fields. Based on the success of an area-wide program in Arizona, as well as results from experiments in South Texas, the granting of this permanent exemption for AF36 will provide a means for Texas cotton producers to reduce their economic losses from aflatoxin contamination of cottonseed. Our association strongly supports the establishment of an exemption for AF36 and urges the EPA to grant its approval.

Sincerely,


Jeff Nunley
Executive Director

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196



Arizona Cotton
Growers Association

07/03-0020-0012

(1P)

Postmark 3/10/03

March 10, 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Application for Establishment of an Exemption from a Tolerance for the Microbial Pesticide
Aspergillus Flavus AF36 and registration of *Aspergillus flavus* AF36

Docket Number ID#OPP-2003-0020

To Whom It May Concern:

The Arizona Cotton Growers Association (ACGA) supports the application for full registration of *Aspergillus flavus* AF36 for use in Arizona and Texas. The Association has been deeply involved in the development and implementation of the technology on Arizona cotton since 1996. During this time the Association has observed the biological and economic benefits of AF36 treatments. Additionally, the Association has received no reports of adverse effects either from its grower community or the public at large under extensive experimental use conditions.

Full-scale utilization of AF36 in both Texas and Arizona is very important to the reduction/elimination of aflatoxin contamination of cotton in these states, where significant economic losses to cotton farming have been reported since the 1960's. This research using non-toxic strains of *Aspergillus flavus* to displace aflatoxin-producing strains also has great potential for other crops such as corn and peanuts and is the only control mechanism of its kind nationwide.

The Arizona Cotton Growers Association urges EPA to grant full registration for *Aspergillus flavus* AF36 for use on commercial cotton fields in Arizona and Texas. If there are questions please contact me at (602) 437-1344.

Sincerely,

Clyde Sharp
President

4139 E. Broadway / Phoenix, Arizona 85040 / (602) 437-1344
FAX (602) 437-5401

19781

(18)

Arizona Department of Agriculture
1688 West Adams
Phoenix, Arizona 85007
Phone: (602) 542-0954 Fax: (602) 542-0466

March 14, 2003

Public Information and Records Integrity Branch
Office of Pesticide Programs
U. S. Environmental Protection Agency (7502C)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

ATTENTION: OPP-2003-0020

The purpose of this letter is to support the exemption from a tolerance and registration of *Aspergillus flavus* AF 36 for use on cotton to reduce populations of other strains of this fungus that produce aflatoxin. Aflatoxin contamination is a chronic problem in cotton grown in our low desert areas. We as a state agency need to administer a comprehensive monitoring program to protect animal feeds from contamination with this substance. While the contamination can be the result of post harvest handling of cottonseed, much of our aflatoxin problem can be traced to preharvest origins.

We feel that use of strain AF 36 as outlined in the experimental use permit 69224-EUP-1 significantly reduces the levels of aflatoxin present at harvest. Once introduced into an area, AF 36 maintains itself over several years, making reapplication unnecessary. This reduces grower costs, a timely bonus given the low prices currently paid for even premium quality cotton. This same attribute of AF 36 makes it unlikely to attract the interest of commercial pesticide producers since a single treatment remains effective over so long a time period, limiting potential sales demand. Availability of AF 36 along with other highly selective and effective pest control options such as genetically engineered cotton and insect growth regulators will enable our growers to produce superior quality cotton utilizing historically low volumes of pesticide.

Sincerely yours,

Edwin W. Minch

Edwin W. Minch
Environmental Specialist
ed.minch@agric.state.az.us

11

2PP



1521 New Hampshire Avenue, NW • Washington, DC
(202) 745-7808 • FAX (202) 483-4040

PRODUCERS • GINNERS • WAREHOUSEMEN • MERCHANTS • CRUSHERS • COOPERATIVES • MANUFACTURERS

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs (OPP)
Environmental protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001
opp-docket@epa.gov
Attention: Docket ID Number OPP-2003-0020

March 14, 2003

Re: Docket ID Number OPP-2003-0020; Comments on *Aspergillus flavus* AF-36
Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a
Pesticide Microbial Agent in or on Food (68 FR 7554; 2-14-03)

Dear Madam or Sir:

The National Cotton Council (NCC) supports this pesticide petition from IR-4 (on behalf of The Arizona Cotton Research and Protection Council, Phoenix, AZ) proposing to amend 40 CFR 180.1206 by establishing an amendment/expansion of an existing tolerance exemption for the non-aflatoxin-producing microbial pesticide *Aspergillus flavus* AF 36 in or on the food and feed commodity cotton and its by-products. NCC is the central trade association of the U.S. cotton industry, representing producers, ginner, oilseed crushers, merchants, cooperatives, warehouses, and textile manufacturers in 18 states. On average, NCC members produce and gin over 17 million bales of cotton and NCC cottonseed members handle over 6.5 million tons of cottonseed for oilseed processing and dairy feeding.

Full Section 3 registration for *A. flavus* AF-36 in both AZ and TX is very important to the economics of cotton production and reduction of toxigenic *Aspergillus flavus* and aflatoxin contamination of cottonseed in AZ and South TX. There are no other management techniques available that control toxigenic *A. flavus* contamination of cotton prior to harvesting. Post-harvest treatments (e.g., ammoniation) are not economical and have not obtained full regulatory approval from the U.S. Food and Drug Administration (FDA). This research using atoxigenic strains of *A. flavus* to displace aflatoxin-producing strains of *A. flavus* represents a scientifically valid biocontrol approach for reducing toxigenic *A. flavus* and aflatoxin contamination and also has great potential for other crops (e.g., corn, peanuts, pistachios, almonds, walnuts, and figs). This fungal material is already

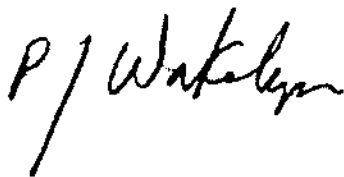
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part of the naturally occurring microflora in the fields in AZ and South Texas and does not increase the amount of *A. flavus* in the field, so there are no unanticipated environmental affects.

Aflatoxin contamination of cottonseed causes significant economic losses (at least \$50/acre) to cotton producers, ginners, brokers, and oil mills in AZ and TX by reducing the value of this commodity (see J. Robens *The Cost of Mycotoxin Management to the USA: Management of Aflatoxins in the United States*, paper presented at Annual Meeting Am. Phytopath. Soc. Aug. 2001). Contamination of cottonseed and cottonseed meal severely restricts its use in feeding. If feed to dairy cattle, the aflatoxin can be metabolized and passed into the milk making the milk an adulterated product, according to the FDA.

NCC urges EPA to grant this petition to amend 40 CFR 180.1206 by establishing an amendment/expansion of an existing tolerance exemption for the non-aflatoxin-producing microbial pesticide *Aspergillus flavus* AF 36 in or on the food and feed commodity cotton and its by-products. This exemption from tolerance should be granted for use on commercial cotton fields in AZ and TX as soon as possible, so that this valuable research can be used on this year. If there are questions please contact me at 202-745-7805 or by e-mail at pwakelyn@cotton.org.

Sincerely,



Phillip J. Wakelyn, Ph.D.
Senior Scientist, Environmental Health and Safety

H

OPP03-0020-0015

Comments Related to the Registration of Aspergillus flavus AF36 as a Microbial Pesticide for the Management of Aflatoxin Contamination:

3PP

Docket ID # OPP-2003-0020

MAR 18 2003

Research:

Postmark 3/14/03

The harmful affects of Aspergillus flavus (Aflatoxin) date back to the 1960's when it was termed the "Turkey X Disease" due to the fact that it killed more than 100,000 young turkeys in England. Today, Humans are exposed to aflatoxins by consuming foods contaminated with products of fungal growth. Such exposure is difficult to avoid because fungal growth in foods is not easy to prevent. Even though heavily contaminated food supplies are not permitted in the market place in developed countries, there are still concerns for the possible adverse effects resulting from long-term exposure to low levels of aflatoxins in the food supply.

Evidence of acute aflatoxicosis in humans has been reported from many parts of the world. The syndrome is characterized by vomiting, abdominal pain, pulmonary edema, convulsions, coma, and death with cerebral edema and fatty involvement of the liver, kidneys, and heart. Conditions increasing the likelihood of acute aflatoxicosis in humans include limited availability of food, environmental conditions that favor fungal development in crops and commodities, and the lack of regulatory systems for aflatoxin monitoring and control.

Aflatoxins are detected occasionally in milk, cheese, corn, peanuts, cottonseed, nuts, almonds, figs, spices, and a variety of other foods and feeds. Milk, eggs, and meat products are sometimes contaminated because of the animal consumption of aflatoxin-contaminated feed. However, the commodities with the highest risk of aflatoxin contamination are corn, peanuts, and cottonseed. Corn is probably the commodity of greatest worldwide concern, because it is grown in climates that are likely to have perennial contamination with aflatoxins and corn is the staple food of many countries.

Although aflatoxins are stable to moderately stable in most food processes, they are unstable in processes such as those used in making tortillas that employ alkaline conditions or oxidizing steps. Aflatoxin-contaminated corn and cottonseed meal in dairy rations have resulted in aflatoxin M1 contaminated milk and milk products, including non-fat dry milk, cheese, and yogurt (Cornell University - Aflatoxins: Occurrence and Health Risks).

Personal View:

According to this information, there should be no reason why the EPA would not grant the registration of the atoxigenic strain *Aspergillus flavus* AF 36. Research clearly shows that aflatoxins are highly toxic for humans and animals. Aflatoxin intoxicates our bodies through respiration and consumption. If we have the ability to control this toxic fungus from its growth, than why not control it.

Aflatoxin has impacted our farm on a very large scale. Over the past several years, we have lost several hundred thousand dollars due to the infestation of aflatoxin on our corn and cotton seed. In many cases, we have had to destroy our entire corn and popcorn crop because of high levels of aflatoxin. Aflatoxin also has a huge impact on the price of cottonseed. With just a trace amount of aflatoxin detected, our cottonseed can not be sold to feedlots for animal consumption.

Aflatoxin has had a tremendous impact on Agriculture as a whole. In the future, aflatoxin will continue to have a negative affect on U.S. Agriculture as long as we allow this toxin to grow uncontrollably.

Sam Sparks
SRS Farms

CPH-0030-0016

YUCO GIN, INC. II

P.O. BOX 5966
YUMA, ARIZONA 85366-5966

TELEPHONE
(928) 329-9955

TELEFAX
(928) 329-9977

18

MAR 12 2003

Postmark 3/13/03

March 13, 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Ave., NW. Washington, DC 20460-000
Attention: Docket ID Number OPP-2-3-0020

To Whom It May Concern:

The purpose of this letter is to voice our full support for the Section 3 registration of *Aspergillus flavus* AF36 (an atoxigenic strain) for the suppression of aflatoxin in cottonseed from Arizona and Texas.

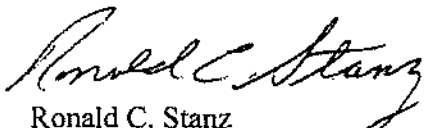
Yuco Gin orchestrated the application of AF36 on a large block of our members cotton in Yuma, Arizona in 2002. Following harvest we ginned and sold 2300 tons of clean seed (< 20 ppb aflatoxin) as opposed to 900 tons the previous season, before the organized use of AF36. This resulted in a significant increase in our profit margin.

Yuco Gin operates in an area where historically high levels of aflatoxin have been the rule rather than the exception. Atoxigenic strain technology offers us an opportunity to return to profitability with increased returns of up to \$40 per ton of cottonseed.

AF36 technology is an environmentally benign approach to aflatoxin control.

We therefore strongly support full registration of AF36 for both Arizona and Texas.

Sincerely,


Ronald C. Stanz
Vice President/General Manager

203/181

4180-CC3C-0017

Grower's Mohawk Gin, Inc.

785-4913
AREA CODE 520

39485 CO. 4TH ST.,

ROLL ARIZONA 85347

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Ave., NW, Washington, DC 20460-000
Attention: docket ID Number OPP-2-3-0020

1 3 2003

Postmark 3/12/03

To Whom It May Concern:

This letter is written in support of the above referenced application for the registration for the use of *Aspergillus flavus* AF36 designed to reduce Aflatoxin contamination of cottonseed.

Present indications reveal that these economic losses can be dramatically reduced, through the use of this biological control method, which does not require the use of synthetic chemicals thereby rendering this method highly environmentally suitable.

Until recently, there has been no technology available for the prevention of Aflatoxin contamination in cottonseed grown on approximately 300,000 acres of cotton in Arizona. The establishment of atoxigenic strain technology (AF36) has already proven to be successful in cotton and could be readily adapted to other agricultural crops such as peanuts and corn, thereby enabling this method to have a greater beneficial economic impact on American agriculture.

At the local level Growers Mohawk Gin has witnessed and increase in clean seed production (less than 20 ppb Aflatoxin) from approximately 20% (before the use of AF36) to 60% in 2002 following widespread utilization of AF36.

For the reasons listed above we strongly recommend a timely approval of the registration process, which would allow *Aspergillus flavus* AF36 to be used commercially throughout Arizona and Texas.

Very truly yours,



Fred Richard
Manager





AF3-0020 0018

Chandler Ginning Co. 1P

MAILING ADDRESS: P. O. Box 3120 Casa Grande, AZ 85222-0120
Phone & Fax (520) 723-4934

A Grower Owned Ginning Association

March 13, 2003

MAE 19 2003

Postmark 3/13/03

LOCATION

5878 North
Eleven Mile Corner Rd

GENERAL MGR:

Jim Gale
Extension # 11

GIN MGR:

Kim Vale
Extension # 12

OFFICE MGR:

Ginny Hoelar
Extension # 10

BOOKKEEPER:

Mike Strong
Extension # 13

BOARD OF DIRECTORS:

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Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Ave., NW, Washington, DC 20460-000
Attention: Docket ID Number OPP-2-3-0020

To Whom It May Concern:

The Arizona Cotton Growers Association wishes to go on record as voicing strong support for an Exemption from Tolerance and for registration of *Aspergillus flavus* AF36 for aflatoxin control in Arizona and Texas.

For more than 30 years high levels of aflatoxin have put Arizona cottonseed at a severe marketing disadvantage. Hundred of millions of dollars in lost revenue have resulted.

The AF36 nontoxic strain technology developed and tested in Arizona is the only method (apart from ammoniation of contaminated seed) which offers relief to our growers. It is an environmentally safe technology which is needed in both Arizona and Texas.

We therefore strongly recommend full registration of AF36 for use in Arizona and Texas.

Sincerely,

Jimmy L. Gale
General Manager

STUDY TYPE: Acute inhalation
Guideline 152-32

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.

JUSTIFICATION:

A waiver is justified because there are no respirable particles in the inerts or End-use Product, inoculated sterilized wheat seeds. Therefore, there is no need for an acute inhalation study. In addition, there were no adverse effects in either of the pulmonary studies

Also please refer to MRID Number and Title of Previously submitted Volumes

- | | |
|----------|---|
| 45798102 | Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100} |
| 45739101 | Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150} |
| 45798101 | Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150} |
| 45798201 | Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150} |
| 43972403 | Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p. |

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Hypersensitivity study
Guideline 152-36

ACTIVE INGREDIENT: *Aspergillus flavus* AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from hypersensitivity studies (Guideline 152-36). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects. There have been no hypersensitivity incidents observed in maximally exposed researchers, handlers during the experimental phases in lab or field. Also no non-occupational exposure above background levels expected based on agricultural use and for all those other reasons listed below. There is already ubiquitous exposure to this naturally occurring organism.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of hypersensitivity testing.

WAIVER REQUEST JUSTIFICATION:

The waiver request is based on the following rationales:

1. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.
2. The use pattern of this product does not include uses on foods for direct human consumption

3. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403
4. An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.
5. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.
6. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.
7. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.
8. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.
9. *Aspergillus flavus* isolate AF36 is a naturally occurring strain of *A. flavus*. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.
10. *Aspergillus flavus* isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil, and is found on living and dead plant material throughout the world. *Aspergillus flavus* is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of *A. flavus* increase during crop production. *A. flavus* occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.
11. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conducive to *A. flavus*. The result is perennially high levels of *A. flavus* on the commercial cottonseed crop. *Aspergillus flavus* isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural *A. flavus* community. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.
12. Application of *A. flavus* AF36 does not increase the quantity of *A. flavus* either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and

45307202.

13. The amount of *A. flavus* being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing *A. flavus* that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed (i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

14. *A. flavus* occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. *A. flavus* is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

Also please refer to MRID Number and Title of Previously submitted Volumes

- 45739104 Antilla, L. ; Cotty, P. ; Braverman, M. (2002) *Aspergillus flavus* Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.
- 43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(*Aspergillus flavus* AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.
- 45307201 Cotty, P. (2001) *Aspergillus flavus* Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of *A. flavus*)
- 43763403 Cotty, P. , Hartman , C. (1995) *Aspergillus flavus* Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of Tolerance for *Aspergillus flavus* for use in Cotton Production
- 45307201 Cotty, P. (2001) *Aspergillus flavus* Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of *A. flavus*)
- 43763403 Cotty, P. , Hartman , C. (1995) *Aspergillus flavus* Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of Tolerance for *Aspergillus flavus* for use in Cotton Production
- 45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: *Aspergillus flavus* AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}

- 45739101 Blanchard, E.; Carter, J. (2002) *Aspergillus flavus* AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}
- 45798101 Blanchard, E. (2002) *Aspergillus flavus* AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}
- 45798201 Blanchard, E. (2002) *Aspergillus flavus* AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin, AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Immune response
Guideline number 152-38.

ACTIVE INGREDIENT: *Aspergillus flavus* AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from immune response studies (152-38). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects. Therefore, testing is not considered necessary to assess the risks of AF-36. The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of immune response testing.

Clearance was observed in both acute oral and pulmonary studies in all organs examined. At no point in the study did any substantial increase in viable counts occur. There was also no trend in body temperature relating to any infective response.

WAIVER REQUEST JUSTIFICATION:

The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403
2. An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.
3. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.
4. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.
5. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.
6. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.
7. *Aspergillus flavus* isolate AF36 is a naturally occurring strain of *A. flavus*. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.
8. *Aspergillus flavus* isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil, and is found on living and dead plant material throughout the world. *Aspergillus flavus* is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of *A. flavus* increase during crop production. *A. flavus* occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.
9. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conducive to *A. flavus*. The result is perennially high levels of *A. flavus* on the commercial cottonseed crop. *Aspergillus flavus* isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural *A. flavus* community. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

10. Application of *A. flavus* AF36 does not increase the quantity of *A. flavus* either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

11. The amount of *A. flavus* being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing *A. flavus* that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed (i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter).

12. *A. flavus* occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. *A. flavus* is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

13. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

14. The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

45739104 Antilla, L. ; Cotty, P. ; Braverman, M. (2002) *Aspergillus flavus* Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats: (*Aspergillus flavus* AF36): Final Report: Lab Project Number: M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) *Aspergillus flavus* Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of *A. flavus*)

43763403 Cotty, P. , Hartman , C. (1995) *Aspergillus flavus* Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of Tolerance for *Aspergillus flavus* for use in Cotton Production

45307201 Cotty, P. (2001) *Aspergillus flavus* Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of *A. flavus*)

43763403 Cotty, P. , Hartman , C. (1995) *Aspergillus flavus* Isolate AF36: Safety Data in

Support of Petition Proposing a Temporary Exemption from the Requirements
of Tolerance for *Aspergillus flavus* for use in Cotton Production

- 45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: *Aspergillus flavus* AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}
- 45739101 Blanchard, E.; Carter, J. (2002) *Aspergillus flavus* AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}
- 45798101 Blanchard, E. (2002) *Aspergillus flavus* AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004; UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}
- 45798201 Blanchard, E. (2002) *Aspergillus flavus* AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin, AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

Spore suspensions in 0.5% Tween 80 were produced on colonized wheat according to the manufacturing protocol.

Turbidity in NTUs (Nephelometric Turbidity Unit) was measured in 50% aqueous ethanol in the same manner as during manufacture of the commercial *Aspergillus flavus* AF36 product.

A 50 ml aliquot of suspension was placed in a tared 60 ml conical centrifuge tube and centrifuged at 3,000 X G at 25 C for 15 minutes.

The supernatant was discarded and the fresh weight of the pellet (composed of fresh conidia) was determined.

The centrifuge tube was covered with filtering cloth (Miracloth) and placed in a forced air oven at 48 C for 5 days.

The mass of the pellet was measured and the weight of spores per NTU unit per ml was calculated to be between 0.0024 mg and 0.0025 mg.

1,000 lbs of dry wheat receives between 1,340,000 and 1,480,000 NTU X ml of spores or from 3,216 mg spores to 3,700 mg spores. The target quantity of spores to add is 3,552 mg per 1,000 lb.

On a percent basis for 100 pounds, 0.355 g of AF36 spores in relation to 45,453.645 g of wheat [AF36 (0.355 g) + wheat (45453.645 g) = 45,454 grams or 100 pounds) is equivalent to 0.0008 % by weight AF36.

Shanaz Bacchus
Biopesticide and Pollution Prevention Division
Room 910
1921 Jefferson Davis Highway
Arlington, VA 22202
(703)308-8097

March 7, 2003

RE: Aspergillus flavus AF-36 in or on Cottonseed
EPA Reg # 71693-R
PP# 8E5001

Dear Shanaz:

The undersigned, Dr. Michael Braveman, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial pesticide, *Aspergillus flavus* AF36 on behalf of the Arizona Cotton Research and Protection Council.

List of information Submitted

8570-1 Form

Data Waivers for Health Effects

Data Waivers for Environmental Effects

Research paper in preparation for Phytopathology by Garcia and Cotty
"Aflatoxin Contamination of Commercial Cottonseed in South Texas"*

Efficacy data for AF-36 Texas as a public interest document*

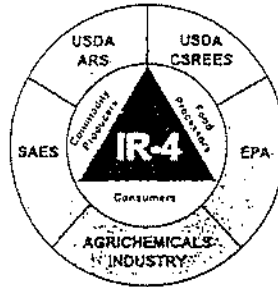
* Note: The Aflatoxin and efficacy data are scientific data supplied by Peter Cotty which are intended for journal publication and should be considered Confidential Business Information until they are actually published

In regard to your questions concerning the use of AF-36 in Texas in proximity to water and the applicability of the waivers granted for Arizona to include Texas, the target for the product is cotton fields. In both Texas and Arizona, cotton is grown in a monoculture. While the overall environment outside of the fields may differ, cultural practices such as ditch and furrow irrigation make the cotton field environments quite similar for AF-36. Because AF-36 is applied as a granule the product should not drift outside of the cotton field. As shown in the attached article "Aflatoxin Contamination of Commercial Cottonseed in South Texas" there is a very high concentration of aflatoxin already present in cotton fields in the Gulf Coast Region. More specifically, "two sub areas showed recurrent high contamination which are immediately adjacent to the Gulf"(page 11). Like Arizona, a delayed harvest in Texas also results in increased aflatoxin contamination(page 15). It was concluded that the Gulf Coast areas of South Texas are areas that should have similar biological control programs to those used in Arizona(Page 17-18) Aflatoxin production in this area is due to the presence of *Aspergillus flavus* that produce the toxin. *Aspergillus flavus* is present on the cotton debris left behind in the field, cotton gin trash placed back on the field which totals about 10,000 pounds of plant debris per acre. *Aspergillus flavus* is also present in corn grown in the Texas Gulf Coast. The ubiquitous nature of *Aspergillus flavus* in the region means that all organisms including fish and other aquatic organisms are already exposed to *Aspergillus flavus* at quantities that vastly exceed the use of the product AF-36. The AF-36 strain is also already found in the soils and plant debris in Texas so there is not any new introduction of the organism. The purpose of applying the product AF-36 is not to increase the amount of *Aspergillus* population. The purpose is to change the proportion of the *Aspergillus* community that is composed of the AF-36 strain of *Aspergillus*. By changing the proportion of the *Aspergillus flavus* that consists of the AF-36 strain, there is a decrease of the toxin producing strains (such as the S strain). Therefore the use of the product AF-36 would not result in any greater exposure of fish or any other aquatic organism to *Aspergillus flavus*. In addition since AF-36 reduces aflatoxin production, the use of AF-36 should decrease the amount of aflatoxin exposure to fish and other aquatic organisms.

Yours very truly,

Michael Braverman, Ph.D.
Interregional Research Project No. 4
Petitioner

Per _____
IR-4 Project Coordinator
IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390



**Interregional Research Project No. 4
Center for Minor Crop Pest Management**

Shanaz Bacchus
Biopesticides and Pollution Prevention Division
Environmental Protection Agency
ROOM 910 (7511 C)
Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202
(703) 308-8097

Dec 23, 2002

RE: *Aspergillus flavus* AF36 aj#006456
Pending Section 3 Registration Number 71693-R, Petition 8E5001

Dear Shanaz:

Attached is an original signed copy of the classification of documents in the "Index of Documents Submitted along with the release letter. Please let me know if you have any questions.

Yours very truly,

Michael Braverman, Ph.D.
Biopesticide Coordinator
Interregional Research Project No. 4
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390
(732) 932-9575 ext 610

CC: Peter Cotty(w/attachment)

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

238

Dr. Michael Braverman
Technology Center of New Jersey
Interregional Research Project No.4 (IR-4)
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Dear Dr. Braverman:

***Aspergillus flavus* AF36 (ai# 006456)**
Pending Section 3 Registration EPA Reg. No. 71693-R
Pesticide Petition 8E5001

A docket has been established for the pending Federal Register documents regarding the application for the Section 3 registration and exemption from tolerance associated for use of *Aspergillus flavus* AF36 on cotton in Arizona and Texas. We are requesting classification from IR-4, Dr. Peter Cotty and all relevant parties regarding the documents listed on the attached indexes. The classification categories are described as follows.

- A= Releasable to Anyone
- B= Releasable to persons who submit a signed Affirmation of Non-multinational Status form. If "B" documents appear on the index, a copy of the Affirmation is attached.
- C= Claimed Confidential by the submitter. Requests for "C" documents will be processed under the Freedom of Information Act and EPA's public information regulations at 40 CFR Part 2, subpart B.

Please fill out the attached form, so that we can quickly finalize these pending Federal Register notices that are essential for the registration of your product. Your assistance is appreciated. If you have any further questions regarding this matter, do not hesitate to email me or call at 703-308-8097.

Sincerely,
/s/

Shanaz Bacchus, Chemist
Regulatory Action Leader
Biopesticides and Pollution Prevention Division

Enclosure

358

1. Michael Braverman Biopesticide Coordinator
(insert name and title) /

of Interregional Research Project No.4 (IR-4) have classified the following documents
pertaining to the Active ingredient *Aspergillus flavus* AF36 as indicated in the attached
tables.

Signature/title/date Michael Braverman 12/20/02
Biopesticide Coordinator
IR-4 Project

Send completed form to:

ATTN: Shanaz Bacchus (7511C)
Biopesticides Pollution Prevention Division
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

458

Index of Documents Submitted

(As of February 8, 2002)

OPP- (Docket #)

Aspergillus flavus AF36; Pending Section 3 Registration 71693-R; Establishment of Permanent tolerance exemption PP# 8E5001

TITLE: (Title of document)	Author: (Last name, First name)	Document Date	Classification
1. Bibliography (attached)	EPA		
2. Application for Section 3 Registration for <i>Aspergillus flavus</i> AF36 for use on cotton in Arizona (AZ), Texas (TX). Form 8570-1	Antilla, Larry	8/8/02	B
3. Transmittal Letter and attachments	Braverman, Michael	8/12/02	B
4. Risk Assessment of <i>Aspergillus</i> <i>flavus</i> AF36 (Federal Register Notice of Filing)	EPA Federal Register Document	TBD	A
5. Petition for a permanent exemption from the requirement of a tolerance for residues of products containing the active ingredient <i>Aspergillus flavus</i> AF36 on cotton (PP8E5001)	Braverman, Michael	8/12/02	C
6. Specific References to Supporting Data for the pesticide petition from IR-4 for <i>Aspergillus flavus</i> AF36, and the pending Section 3 registration for (EPA File Symbol 71693-R; PP8E5001; OPP Identifier Number(s)). See references below.	See attached bibliography	See attached bibliography	C

Michael Braverman 12/20/02

508

TITLE: (Title of document)	Classification
<p>43763400 USDA/ARS and IR-4 (1995) Submission of Product Chemistry, Toxicity, and Risk Data in Support of an Experimental Use Permit for <i>Aspergillus flavus</i> AF36. Transmittal of 5 Studies. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575</p>	C
<p>43763401 Cotty, P. (1995) <i>Aspergillus flavus</i> Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575</p>	C
<p>43763402 Cotty, P. (1995) <i>Aspergillus flavus</i> Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575</p>	C
<p>43763403 Cotty, P.; Hartman, C. (1995) <i>Aspergillus flavus</i> Isolate AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for <i>Aspergillus flavus</i> for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575</p>	C
<p>43763404 Cotty, P. (1995) <i>Aspergillus flavus</i> Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding No Hypersensitivity: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 4 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575</p>	C
<p>43763405 Cotty, P.; Hartman, C. (1995) <i>Aspergillus flavus</i> Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575</p>	C

Michael Braverman 12/20/02

608

TITLE: (Title of document)	Classification
43972400 Interregional Research Project No. 4 (1996) Submission of Product Analysis and Toxicology Data in Support of an Experimental Use Permit for <i>Aspergillus flavus</i> AF36. Transmittal of 3 Studies. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972401 Cotty, P. (1996) <i>Aspergillus flavus</i> Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 1 to MRID No. 43763404: Lab Project Number: PR 52B: 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 6 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972402 Cotty, P. (1996) <i>Aspergillus flavus</i> Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity: Amendment No. 1 to MRID No. 43763404: Lab Project Number: 52B: PR 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 4 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972403 Shelton, L. (1996) Acute Oral Toxicity Study in Rats: (<i>Aspergillus flavus</i> AF36): Final Report: Lab Project Number: M96AG84.6G31: MA M96AG84.6G31. Unpublished study prepared by Microbiological Associates, Inc. 59 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43990000 Interregional Research Project No. 4 (1996) Submission of Product Chemistry Data in Support of the Application for Experimental Use Permit for <i>Aspergillus flavus</i> AF36. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 069224EX1	C
43990001 Cotty, P. (1996) <i>Aspergillus flavus</i> Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process, and Discussion on the Formation of Unintentional Ingredients: Amendment No. 1 to MRID 43763401: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS, Southern Regional Research Center. 6 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
44597000 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of <i>Aspergillus flavus</i> isolate AF36 in/on Wheat. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 8E5001	C

798

TITLE: (Title of document)	Classification
<p>44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p. SUBMITTED IN SUPPORT OF: 8E5001</p>	<p>C</p>
<p>44626100 Interregional Research Project No. 4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Cotton. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575</p>	<p>C</p>
<p>44626101 Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575</p>	<p>C</p>
<p>44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 8E5001 SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1</p>	<p>C</p>
<p>44713701 Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p. SUBMITTED IN SUPPORT OF: 8E5001 SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1</p>	<p>C</p>

Michael Braverman 12/20/02

828

TITLE: (Title of document)	Classification
<p>45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of <i>Aspergillus flavus</i> Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies.</p> <p>SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1</p>	C
<p>45307201 Cotty, P. (2001) <i>Aspergillus flavus</i> Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of <i>A. flavus</i>): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.</p> <p>SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1</p> <p>Start here</p>	C
<p>45739100 Interregional Research Project No. 4 (2002) Submission of Toxicity and Exposure Data in Support of the Petition for Tolerance of <i>Aspergillus flavus</i> on Cotton. Transmittal of 4 Studies.</p> <p>SUBMITTED IN SUPPORT OF: 2E6497</p> <p>45739103 Smith, D.; Cotty, P.; Braverman, M.; et al. (2002) <i>Aspergillus flavus</i> Isolate AF36: Non-Target Organism and Environmental Safety Information: Lab Project Number: IR-4 PR NO.52B: Unpublished study prepared by Soil & Crop Sciences, Southern Regional Research Center USDA/ARS, Rutgers University and Arizona Cotton Research and Protection Council. 57 p.</p> <p>SUBMITTED IN SUPPORT OF: 8E5001</p>	C
<p>45739101 Blanchard, E.; Carter, J. (2002) <i>Aspergillus flavus</i> AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}</p> <p>SUBMITTED IN SUPPORT OF: 8E5001</p>	C

Michael Braverman 12/20/02

00003-0020-0001

A TUMBLING T RANCHES
14929 W. Broadway Rd.
GOODYEAR, AZ 85338
Office (623)932-1834 Fax (623)932-3170
ATTRCH@aol.com

(1P)

March 7 2003

March 5/7/03

Public Information & Records Integrity Branch (7502C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW, Washington, DC 20460-000
Attention: Docket ID #OPP-2-3-0020

March 7, 2003

To Whom It May Concern:

This letter is my written comment on the application for an exemption from a tolerance and for registration of *Aspergillus flavus* AF36 for the prevention of aflatoxin contamination of cottonseed in Arizona.

I am a cotton farmer and the president of Farmers Gin, Inc. Historically, more than 50 percent of the cottonseed produced at our gin has tested higher than 20 ppb of aflatoxin. The majority of our 12,000 ton annual production goes to the dairy feed market. I estimate our losses at more than \$100,000 per year due to the higher levels.

High levels of aflatoxin are a serious problem in Arizona. The high levels reduced the value of the seed and place the seller at risk legally if subsequent tests show higher levels of contamination than that certified at the time of the sale. Several lawsuits and state regulatory administrative actions have occurred in recent years pitting dairymen and regulators against seed brokers, gins and cotton farmers.

There are no products currently on the market that will reduce or prevent aflatoxin contamination in any crop. There are also no cultural practices or biological controls that help reduce the levels.

The registration of *Aspergillus flavus* AF36 will be the first product available for reducing aflatoxin contamination of cottonseed. This product is needed by the industry in Arizona and in Texas as well.

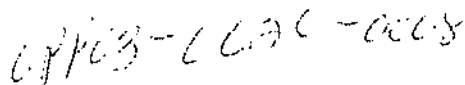
I am pleased to hear that the product is not a synthetic chemical, but a naturally occurring strain of *Aspergillus* that does not produce aflatoxin and replaces the strains that do.

I strongly support the registration of AF36.

Sincerely,



F. Ronald Rayner
President
Farmers Gin, Inc.



IP

March 6, 2003

MAR 15 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Avenue NW
Washington DC 20460

Postmark 3/6/03

To Whom It May Concern:


The Anderson Clayton Corporation conducts extensive cottonseed ginning and sales operations in Arizona where aflatoxin contamination has plagued growers for more than 30 years. This contamination has resulted in lost revenue and profit to Anderson Clayton, its raw material suppliers (cotton producers) and cottonseed feeders (primarily dairies) and cottonseed products consumers (again, primarily dairy, but other feed consumers as well).

The extraordinary fluctuations of aflatoxin contamination have resulted in losses for Arizona cotton producers in the millions of dollars.

It is our experience that no products are approved or even currently exist for treatment of any crop to prevent aflatoxin contamination in the field. *Aspergillus flavus* AF36, a biological control using no synthetic chemicals, is the first product available for reducing such contamination in cottonseed.

As a company that has directly and indirectly been affected by aflatoxin contamination of cottonseed, we have long tracked and supported the USDA ARS work conducted by Dr. Peter Cotty on aflatoxin in cottonseed and other agricultural commodities. Having seen first hand the negative financial exposure and impact aflatoxin contamination can have on our customers as well as our company, we strongly urge registration of *Aspergillus flavus* AF36 on cotton in Arizona and Texas.

Sincerely,



Jeffery J. Ballentine
V. P. Arizona Operations



Texas Agricultural Experiment Station

THE TEXAS A&M UNIVERSITY SYSTEM

10345 Agnes St.
Corpus Christi, TX 78406-1412
Phone: 361/265-9201 Fax: 361/265-9434
Web: <http://ccag.tamu.edu>

Agricultural Research and Extension Center at Corpus Christi

March 3, 2003

(1P)

Public Information and Records Integrity Branch
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460-000

Postmarked 3/3/03

Attention: Docket ID Number OPP-2003-0020

This letter is in support of the application for Establishment of an Exemption from a Tolerance for the Microbial Pesticide *Aspergillus flavus* AF36 under Docket ID Number OPP-2003-0020. My comments relate to the registration of *Aspergillus flavus* AF36 as a microbial pesticide for the management of aflatoxin contamination in cottonseed.

We have serious problems with aflatoxin contamination of cottonseed in the gulf coast region of Texas causing millions of dollars in losses annually from sales and uses of cottonseed products in ruminant animal feeding. Serious problems also occur in cottonseed in other parts of Texas and in Arizona. Currently there are no alternatives to *Aspergillus flavus* for preventing aflatoxin contamination in cottonseed. Since there are no products currently available for preventing aflatoxin contamination in cottonseed or on any other crop, *Aspergillus flavus* AF36 is a product needed by the cotton industry in Texas and Arizona. We hope to have the opportunity to use *Aspergillus flavus* AF36 in developing effective control mechanisms to prevent aflatoxin contamination in cotton crops for our producers, the single most economically important crop produced in the lower gulf coast of Texas.

Thank you for consideration of this request.

Sincerely,

Bobby R. Eddleman, Ph.D.
Resident Director of Research
Texas Agricultural Experiment Station
Texas A&M University Agricultural
Research & Extension Center
10345 Agnes St.
Corpus Christi, TX. 78406

181



Texas Cooperative
EXTENSION

The Texas A&M University System

348 Soil and Crop Sciences • College Station, Texas 77843-2474 • (979) 845-2425 • FAX (979) 845-0604

OPP03-0020-0020

JP

March 7, 2003

10 2003

pastmark 3/11/03

Public Information and Records Integrity Branch (7502C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-000

RE: Docket ID Number OPP-2003-0020

This letter provides my support for establishment of an exemption from a tolerance for the microbial pesticide *Aspergillus flavus* AF36. AF36 is the first and only biological control method for eliminating aflatoxin contamination from cottonseed, and I strongly support the exemption.

Texas annually harvests between four and five million bales of cotton. Due to environmental conditions, several production regions face perennial problems from aflatoxin contaminated cottonseed. These regions include central Texas (Blackland Prairie and Bottomlands) which produces about 230,000 bales, the south Texas region (Upper Gulf Coast and Coastal Bend) which generates over 700,000 bales, and the Rio Grande Valley area which generates over 200,000 bales. Together these areas support the production of over 1.1 million bales.

According to information provided by the "Office of the State Chemist", cottonseed from these three regions will generally test positive for aflatoxin, and between 15 to 80% of the cottonseed will exceed 20 ppb. As an example, in 1997 and 1998 over 80% of the cottonseed from these regions tested greater than 20 ppb, and in 2001 less than 15% exceeded 20 ppb. When aflatoxin levels in cottonseed exceed the 20 ppb limit, the value of the seed is severely discounted (in most cases by greater than 50%), translating into several million dollars lost to producers and the cottonseed industry. Moreover, due to extremely low prices for cotton lint in current and near-future markets, any discounts in cottonseed value further reduces profitability at the farm level.

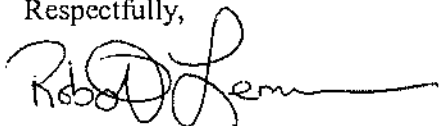
Presently, there are no known means of reducing/eliminating aflatoxin contamination on any crop. The use of atoxigenic strains of *Aspergillus flavus* have proven to be very effective in combating aflatoxin problems in Arizona. Considerable cumulative acres have been treated in Arizona with

no reported adverse effects. Multi-year air sampling studies have demonstrated that the atoxigenic strain AF36 has displaced the aflatoxin producing strains with no increase in total fungus in the environment.

Recent research conducted in the Coastal Bend region of Texas in 2000, 2001 and 2002 with the AF36 strain has also been very successful. However, these studies were limited to small acreages. Consequently, it is critical to the future success of the project to expand this effort and to establish a permanent exemption from tolerance for residues of *Aspergillus flavus* AF36.

Based on previous research in Arizona and Texas, and the success of the area-wide program in Arizona, the granting of this permanent exemption for AF36 will serve as a major step in reducing aflatoxin problems in Texas cottonseed. I strongly support the exemption for AF36 and urge the EPA to grant its approval.

Respectfully,



Robert G. Lemon
Associate Professor
and Extension Agronomist – Cotton
Department of Soil and Crop Sciences
Texas A&M University
College Station, Texas 77843-2474
r-lemon@tamu.edu

cc: Dr. Travis Müller
Dr. Mark Hussey
Dr. Peter Cotty
Dr. James Supak
Mr. Jeff Nunley



South Texas Cotton and Grain Association, Inc.

P.O. Box 4881 • Victoria, Texas 77903-4881 • Telephone: (361) 575-0631 • Fax: (361) 572-0960

March 13, 2003

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

MAR 19 2003

Received 3/13/03

RE: Docket ID Number OPP-2003-0020

South Texas Cotton and Grain Association submits these comments to strongly support the application for **Establishment of an Exemption from a Tolerance for the Microbial Pesticide Aspergillus flavus AF36**.

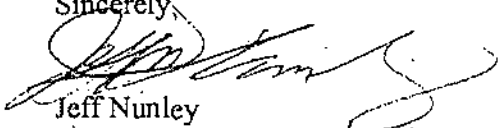
South Texas Cotton and Grain Association is a trade association representing producer members who farm cotton and grain crops in the 33 counties in the Coastal Bend of South Texas. Cotton is a primary crop for our producers and cottonseed is a valuable byproduct of cotton production.

Aflatoxin is a perennial problem for farmers in South Texas and contamination of cottonseed costs producers millions of dollars each year in lost of value. Work done in Arizona has shown that applying atoxigenic strain AF36, which occurs naturally in fields, is effective in reducing the amount of aflatoxin in cottonseed by displacing toxin producing strains (especially the S-strain of *Aspergillus flavus*) without increasing the total amount of fungus in the environment.

Texas is similar to Arizona in that the atoxigenic strain AF36 occurs naturally in South Texas fields. Texas is also similar to Arizona in that the S-strain of *Aspergillus flavus* is the primary cause of aflatoxin contamination in cottonseed. Experiments in Texas using very small test plots have shown that applying *Aspergillus flavus* AF36 is effective in reducing the level of the S-strain.

Presently, there are no alternative methods available to producers to reduce aflatoxin producing fungi in cotton fields. Based on the success of an area-wide program in Arizona, as well as results from experiments in South Texas, the granting of this permanent exemption for AF36 will provide a means for Texas cotton producers to reduce their economic losses from aflatoxin contamination of cottonseed. Our association strongly supports the establishment of an exemption for AF36 and urges the EPA to grant its approval.

Sincerely,


Jeff Nunley
Executive Director



Arizona Cotton
Growers Association

1/13-0020-0012

1P

Postmark 3/10/03

March 10, 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Application for Establishment of an Exemption from a Tolerance for the Microbial Pesticide
Aspergillus Flavus AF36 and registration of *Aspergillus flavus* AF36

Docket Number ID#OPP-2003-0020

To Whom It May Concern:

The Arizona Cotton Growers Association (ACGA) supports the application for full registration of *Aspergillus flavus* AF36 for use in Arizona and Texas. The Association has been deeply involved in the development and implementation of the technology on Arizona cotton since 1996. During this time the Association has observed the biological and economic benefits of AF36 treatments. Additionally, the Association has received no reports of adverse effects either from its grower community or the public at large under extensive experimental use conditions.

Full-scale utilization of AF36 in both Texas and Arizona is very important to the reduction/elimination of aflatoxin contamination of cotton in these states, where significant economic losses to cotton farming have been reported since the 1960's. This research using non-toxic strains of *Aspergillus flavus* to displace aflatoxin-producing strains also has great potential for other crops such as corn and peanuts and is the only control mechanism of its kind nationwide.

The Arizona Cotton Growers Association urges EPA to grant full registration for *Aspergillus flavus* AF36 for use on commercial cotton fields in Arizona and Texas. If there are questions please contact me at (602) 437-1344.

Sincerely,

Clyde Sharp
President

4139 E. Broadway / Phoenix, Arizona 85040 / (602) 437-1344
FAX (602) 437-5401

270/81

611-203-6226 6/17

(1P)

Arizona Department of Agriculture
1688 West Adams
Phoenix, Arizona 85007
Phone: (602) 542-0954 Fax: (602) 542-0466

March 14, 2003

Public Information and Records Integrity Branch
Office of Pesticide Programs
U. S. Environmental Protection Agency (7502C)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

ATTENTION: OPP-2003-0020

The purpose of this letter is to support the exemption from a tolerance and registration of *Aspergillus flavus* AF 36 for use on cotton to reduce populations of other strains of this fungus that produce aflatoxin. Aflatoxin contamination is a chronic problem in cotton grown in our low desert areas. We as a state agency need to administer a comprehensive monitoring program to protect animal feeds from contamination with this substance. While the contamination can be the result of post harvest handling of cottonseed, much of our aflatoxin problem can be traced to preharvest origins.

We feel that use of strain AF 36 as outlined in the experimental use permit 69224-EUP-1 significantly reduces the levels of aflatoxin present at harvest. Once introduced into an area, AF 36 maintains itself over several years, making reapplication unnecessary. This reduces grower costs, a timely bonus given the low prices currently paid for even premium quality cotton. This same attribute of AF 36 makes it unlikely to attract the interest of commercial pesticide producers since a single treatment remains effective over so long a time period, limiting potential sales demand. Availability of AF 36 along with other highly selective and effective pest control options such as genetically engineered cotton and insect growth regulators will enable our growers to produce superior quality cotton utilizing historically low volumes of pesticide.

Sincerely yours,

Edwin W. Minch

Edwin W. Minch
Environmental Specialist
ed.minch@agric.state.az.us

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2PP



1521 New Hampshire Avenue, NW • Washington, DC
(202) 745-7805 • FAX (202) 483-4040

PRODUCERS • GINNERS • WAREHOUSEMEN • MERCHANTS • CRUSHERS • COOPERATIVES • MANUFACT

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs (OPP)
Environmental protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001
opp-docket@epa.gov
Attention: Docket ID Number OPP-2003-0020

March 14, 2003

**Re: Docket ID Number OPP-2003-0020; *Comments on Aspergillus flavus AF-36*
Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a
*Pesticide Microbial Agent in or on Food (68 FR 7554; 2-14-03)***

Dear Madam or Sir:

The National Cotton Council (NCC) supports this pesticide petition from IR-4 (on behalf of The Arizona Cotton Research and Protection Council, Phoenix, AZ) proposing to amend 40 CFR 180.1206 by establishing an amendment/expansion of an existing tolerance exemption for the non-aflatoxin-producing microbial pesticide *Aspergillus flavus* AF 36 in or on the food and feed commodity cotton and its by-products. NCC is the central trade association of the U.S. cotton industry, representing producers, ginner, oilseed crushers, merchants, cooperatives, warehouses, and textile manufacturers in 18 states. On average, NCC members produce and gin over 17 million bales of cotton and NCC cottonseed members handle over 6.5 million tons of cottonseed for oilseed processing and dairy feeding.

Full Section 3 registration for *A. flavus* AF-36 in both AZ and TX is very important to the economics of cotton production and reduction of toxigenic *Aspergillus flavus* and aflatoxin contamination of cottonseed in AZ and South TX. There are no other management techniques available that control toxigenic *A. flavus* contamination of cotton prior to harvesting. Post-harvest treatments (e.g., ammoniation) are not economical and have not obtained full regulatory approval from the U.S. Food and Drug Administration (FDA). This research using atoxigenic strains of *A. flavus* to displace aflatoxin-producing strains of *A. flavus* represents a scientifically valid biocontrol approach for reducing toxigenic *A. flavus* and aflatoxin contamination and also has great potential for other crops (e.g., corn, peanuts, pistachios, almonds, walnuts, and figs). This fungal material is already

part of the naturally occurring microflora in the fields in AZ and South Texas and does not increase the amount of *A. flavus* in the field, so there are no unanticipated environmental affects.

Aflatoxin contamination of cottonseed causes significant economic losses (at least \$50/acre) to cotton producers, ginners, brokers, and oil mills in AZ and TX by reducing the value of this commodity (see J. Robens *The Cost of Mycotoxin Management to the USA: Management of Aflatoxins in the United States*, paper presented at Annual Meeting Am. Phytopath. Soc. Aug. 2001). Contamination of cottonseed and cottonseed meal severely restricts its use in feeding. If feed to dairy cattle, the aflatoxin can be metabolized and passed into the milk making the milk an adulterated product, according to the FDA.

NCC urges EPA to grant this petition to amend 40 CFR 180.1206 by establishing an amendment/expansion of an existing tolerance exemption for the non-aflatoxin-producing microbial pesticide *Aspergillus flavus* AF 36 in or on the food and feed commodity cotton and its by-products. This exemption from tolerance should be granted for use on commercial cotton fields in AZ and TX as soon as possible, so that this valuable research can be used on this year. If there are questions please contact me at 202-745-7805 or by e-mail at pwakelyn@cotton.org.

Sincerely,



Phillip J. Wakelyn, Ph.D.
Senior Scientist, Environmental Health and Safety

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OPP03-0020-0015

Comments Related to the Registration of *Aspergillus flavus* AF36 as a Microbial Pesticide for the Management of Aflatoxin Contamination:

2PP

Docket ID # OPP-2003-0020

MAR 18 2003

Research:

Postmark 3/14/03

The harmful affects of *Aspergillus flavus* (Aflatoxin) date back to the 1960's when it was termed the "Turkey X Disease" due to the fact that it killed more than 100,000 young turkeys in England. Today, Humans are exposed to aflatoxins by consuming foods contaminated with products of fungal growth. Such exposure is difficult to avoid because fungal growth in foods is not easy to prevent. Even though heavily contaminated food supplies are not permitted in the market place in developed countries, there are still concerns for the possible adverse effects resulting from long-term exposure to low levels of aflatoxins in the food supply.

Evidence of acute aflatoxicosis in humans has been reported from many parts of the world. The syndrome is characterized by vomiting, abdominal pain, pulmonary edema, convulsions, coma, and death with cerebral edema and fatty involvement of the liver, kidneys, and heart. Conditions increasing the likelihood of acute aflatoxicosis in humans include limited availability of food, environmental conditions that favor fungal development in crops and commodities, and the lack of regulatory systems for aflatoxin monitoring and control.

Aflatoxins are detected occasionally in milk, cheese, corn, peanuts, cottonseed, nuts, almonds, figs, spices, and a variety of other foods and feeds. Milk, eggs, and meat products are sometimes contaminated because of the animal consumption of aflatoxin-contaminated feed. However, the commodities with the highest risk of aflatoxin contamination are corn, peanuts, and cottonseed. Corn is probably the commodity of greatest worldwide concern, because it is grown in climates that are likely to have perennial contamination with aflatoxins and corn is the staple food of many countries.

Although aflatoxins are stable to moderately stable in most food processes, they are unstable in processes such as those used in making tortillas that employ alkaline conditions or oxidizing steps. Aflatoxin-contaminated corn and cottonseed meal in dairy rations have resulted in aflatoxin M1 contaminated milk and milk products; including non-fat dry milk, cheese, and yogurt (Cornell University - Aflatoxins: Occurrence and Health Risks).

Personal View:

According to this information, there should be no reason why the EPA would not grant the registration of the atoxigenic strain *Aspergillus flavus* AF 36. Research clearly shows that aflatoxins are highly toxic for humans and animals. Aflatoxin intoxicates our bodies through respiration and consumption. If we have the ability to control this toxic fungus from its growth, than why not control it.

Aflatoxin has impacted our farm on a very large scale. Over the past several years, we have lost several hundred thousand dollars due to the infestation of aflatoxin on our corn and cotton seed. In many cases, we have had to destroy our entire corn and popcorn crop because of high levels of aflatoxin. Aflatoxin also has a huge impact on the price of cottonseed. With just a trace amount of aflatoxin detected, our cottonseed can not be sold to feedlots for animal consumption.

Aflatoxin has had a tremendous impact on Agriculture as a whole. In the future, aflatoxin will continue to have a negative affect on U.S. Agriculture as long as we allow this toxin to grow uncontrollably.

Sam Sparks
SRS Farms

01102-0030-0016

YUCO GIN, INC. II

P.O. BOX 5966
YUMA, ARIZONA 85366-5966

TELEPHONE
(928) 329-9955

TELEFAX
(928) 329-9977

March 13, 2003

MAR 13 2003

Postmark 3/13/03

18

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Ave., NW. Washington, DC 20460-000
Attention: Docket ID Number OPP-2-3-0020

To Whom It May Concern:

The purpose of this letter is to voice our full support for the Section 3 registration of *Aspergillus flavus* AF36 (an atoxigenic strain) for the suppression of aflatoxin in cottonseed from Arizona and Texas.

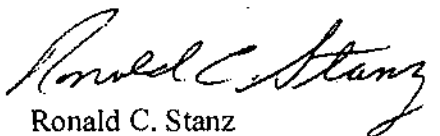
Yuco Gin orchestrated the application of AF36 on a large block of our members cotton in Yuma, Arizona in 2002. Following harvest we ginned and sold 2300 tons of clean seed (< 20 ppb aflatoxin) as opposed to 900 tons the previous season, before the organized use of AF36. This resulted in a significant increase in our profit margin.

Yuco Gin operates in an area where historically high levels of aflatoxin have been the rule rather than the exception. Atoxigenic strain technology offers us an opportunity to return to profitability with increased returns of up to \$40 per ton of cottonseed.

AF36 technology is an environmentally benign approach to aflatoxin control.

We therefore strongly support full registration of AF36 for both Arizona and Texas.

Sincerely,


Ronald C. Stanz
Vice President/General Manager

276/81

6872-0020-0017

Grower's Mohawk Gin, Inc.

785-4913
AREA CODE 520

39485 CO. 4TH ST.,

ROLL ARIZONA 85347

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Ave., NW, Washington, DC 20460-000
Attention: docket ID Number OPP-2-3-0020

Postmark 3/12/03

To Whom It May Concern:

This letter is written in support of the above referenced application for the registration for the use of *Aspergillus flavus* AF36 designed to reduce Aflatoxin contamination of cottonseed.

Present indications reveal that these economic losses can be dramatically reduced, through the use of this biological control method, which does not require the use of synthetic chemicals thereby rendering this method highly environmentally suitable.

Until recently, there has been no technology available for the prevention of Aflatoxin contamination in cottonseed grown on approximately 300,000 acres of cotton in Arizona. The establishment of atoxigenic strain technology (AF36) has already proven to be successful in cotton and could be readily adapted to other agricultural crops such as peanuts and corn, thereby enabling this method to have a greater beneficial economic impact on American agriculture.

At the local level Growers Mohawk Gin has witnessed and increase in clean seed production (less than 20 ppb Aflatoxin) from approximately 20% (before the use of AF36) to 60% in 2002 following widespread utilization of AF36.

For the reasons listed above we strongly recommend a timely approval of the registration process, which would allow *Aspergillus flavus* AF36 to be used commercially throughout Arizona and Texas.

Very truly yours,

Fred Richard

Fred Richard
Manager



07/13-0020 0018



Chandler Ginning Co.

11P

MAILING ADDRESS: P. O. Box 3120 Casa Grande, AZ 85222-0120
Phone & Fax (520) 723-4934

A Grower Owned Ginning Association

March 13, 2003

145 19 2003

Postmark 3/13/03

LOCATION

S878 North
Eleven Mile Corner Rd

GENERAL MGR:

Jim Gale
Extension # 11

GIN MGR:

Kim Vale
Extension # 12

OFFICE MGR:

Ginny Hoeft
Extension # 10

BOOKKEEPER:

Mike Strong
Extension # 13

BOARD OF DIRECTORS:

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Le Smith

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Ave., NW, Washington, DC 20460-000
Attention: Docket ID Number OPP-2-3-0020

To Whom It May Concern:

The Arizona Cotton Growers Association wishes to go on record as voicing strong support for an Exemption from Tolerance and for registration of *Aspergillus flavus* AF36 for aflatoxin control in Arizona and Texas.

For more than 30 years high levels of aflatoxin have put Arizona cottonseed at a severe marketing disadvantage. Hundred of millions of dollars in lost revenue have resulted.

The AF36 nontoxic strain technology developed and tested in Arizona is the only method (apart from ammoniation of contaminated seed) which offers relief to our growers. It is an environmentally safe technology which is needed in both Arizona and Texas.

We therefore strongly recommend full registration of AF36 for use in Arizona and Texas.

Sincerely,

Jimmy L. Gale
General Manager

181



Chandler Ginning Co.

MAILING ADDRESS: P. O. Box 3120 Casa Grande, AZ 85222-0120
Phone & Fax (520) 723-4934

A Grower Owned Ginning Association

March 26, 2003

AF36 - 2003

LOCATION

5878 North
Eleven Mile Corner Rd

GENERAL MGR:

Gale
Extension # 11

GIN MGR:

Kim Valo
Extension # 12

OFFICE MGR:

Ginny Hoefar
Extension # 10

BOOKKEEPER:

Mike Strong
Extension # 13

**BOARD OF
DIRECTORS:**

President:

Mark Pace

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Scott Riggins

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Dan Thelander

Treasurer:

Lee Tregaskes

Mark Dobson
Max Koepnick
Marcus Martin
George Peterson
Le Smith

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Ave., NW,
Washington, DC 20460-0001

RE: Docket ID Number OPP-2003-0048; *Aspergillus flavus* AF36
Registration Application (68 FR11841; 3-12-03)

Dear Sir or Madam:

The Arizona Cotton Ginners Association supports the above referenced application for the registration for the use of *Aspergillus flavus* AF36 designed to reduce aflatoxin contamination of cottonseed.

Field research demonstrates that economic losses can be dramatically reduced through the use of this promising biological control method. Because it eliminates the use of synthetic chemicals, it is both user and environmentally friendly.

Until recently, there has been no technology available for the prevention of aflatoxin contamination in cottonseed grown on approximately 300,000 acres of cotton in Arizona. The establishment of atoxigenic strain technology (AF36) has already proven to be successful in cotton and could be readily adapted to other agricultural crops such as peanuts and corn, thereby enabling this method to have an enhanced beneficial economic impact on American agriculture.

Several member gins of our Association have experienced very positive results as a result of AF36 use by the growers. For this and the other reasons listed above we strongly recommend a timely approval of the registration process which would allow *Aspergillus flavus* AF36 to be used commercially throughout Arizona and Texas.

Very truly yours,

Mark Pace, Az Cotton

X

88703-0048-0008

FARMER'S GIN, INC.

3825 S. 99TH AVE • TOLLESON, ARIZONA 85353 • OFFICE: (623) 936-8505 • GIN: (623) 386-2020 OR (623) 386-5899

March 26, 2003

(1P)

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

APR - 1 2003

Postmarked 3/26/03

Re: Docket ID Number OPP-2003-0048; *Aspergillus flavus* AF36 Registration
Application (68-FR11841;3-12-03)

Dear Sir or Madam:

This letter is my written comment on the application for registration of *Aspergillus flavus* AF36 for the prevention of aflatoxin contamination of cottonseed in Arizona.

I am a cotton farmer and the President of Farmer's Gin, Inc. Historically, over 50 percent of the cottonseed produced at our gin has tested higher than 20 ppb of aflatoxin. The majority of our 12,000 ton annual production goes to the dairy feed market. I estimate our losses at \$100,000 per year due to the higher levels.

High levels of aflatoxin are a serious problem in Arizona. The high levels reduced the value of the seed and place the seller at risk legally if subsequent tests show higher levels of contamination than that certified at the time of the sale. Several lawsuits and state regulatory administrative actions have occurred in recent years pitting dairymen and regulators against seed brokers, gins and cotton farmers.

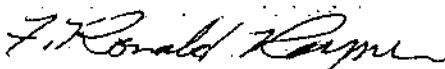
There are no products currently on the market that will reduce or prevent aflatoxin contamination in any crop. There are also no cultural practices or biological controls that help reduce the levels.

The registration of *Aspergillus flavus* AF36 will be the first product available for reducing aflatoxin contamination of cottonseed. This product is needed by the industry in Arizona and in Texas as well.

I am pleased to hear that the product is not a synthetic chemical, but a naturally occurring strain of *Aspergillus* that does not produce aflatoxin and replaces the strains that do.

I strongly support the registration of AF36.

Sincerely,


F. Ronald Rayner, President

H

61763-C-48-0007

AC

Anderson Clayton Corp.

2226 W. NORTHERN AVE., SUITE C201 • PHOENIX, AZ 85021
PHONE (602) 841-2111 • FAX (602) 841-2444

(1P)

March 27, 2003

APR - 1 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Received 3/27/03

RE: Docket ID Number OPP-2003-0048: *Aspergillus flavus* AF36 Registration Application
(68 FR 11841; 3-12-03)

Dear Sir or Madam:

The Anderson Clayton Corporation is writing to support the registration of *Aspergillus flavus* AF36 for the control of aflatoxin in Arizona cottonseed.

Our company conducts extensive cottonseed ginning and sales operations in Arizona where aflatoxin contamination has plagued growers for more than 30 years. This contamination has resulted in lost revenue and profit to Anderson Clayton, its raw material suppliers (cotton producers) and cottonseed feeders (primarily dairies) and cottonseed products consumers (again, primarily dairy, but other feed consumers as well).

The extraordinary fluctuations of aflatoxin contamination have resulted in losses for Arizona cotton producers in the millions of dollars.

It is our experience that no products are approved or even currently exist for treatment of any crop to prevent aflatoxin contamination in the field. *Aspergillus flavus* AF36, a biological control using no synthetic chemicals, is the first product available for reducing such contamination in cottonseed.

As a company that has directly and indirectly been affected by aflatoxin contamination of cottonseed, we have long tracked and supported the USDA ARS work conducted by Dr. Peter Cotty on aflatoxin in cottonseed and other agricultural commodities. Having seen first hand the negative financial exposure and impact aflatoxin contamination can have on our customers as well as our company, we strongly urge registration of *Aspergillus flavus* AF36 on cotton in Arizona and Texas.

Sincerely,



Jeffery J. Ballentine
V. P. Arizona Operations

K
Grower's Mohawk Gin, Inc.

6PP-2003-0048-0010

785-4913
AREA CODE 520

39485 CO. 4TH ST.,

ROLL ARIZONA 85347

PP

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Ave., NW,
Washington, DC 20460-0001

APR 2 2003

postmark 3-28-03

RE: Docket ID Number OPP-2003-0048; *Aspergillus flavus* AF36
Registration Application (68 FR11841; 3-12-03)

Dear Sir or Madam:

This letter is written in support of the above referenced application for the registration for the use of *Aspergillus flavus* AF36 designed to reduce aflatoxin contamination of cottonseed.

Present indications reveal that economic losses can be dramatically reduced through the use of this biological control method which does not require the use of synthetic chemicals thereby rendering this method highly environmentally suitable.

Until recently, there has been no technology available for the prevention of aflatoxin contamination in cottonseed grown on approximately 300,000 acres of cotton in Arizona. The establishment of atoxigenic strain technology (AF36) has already proven to be successful in cotton and could be readily adapted to other agricultural crops such as peanuts and corn, thereby enabling this method to have an enhanced beneficial economic impact on American agriculture.

At the local level Growers Mohawk Gin has witnessed an increase in clean seed production (less than 20 ppb aflatoxin) from approximately 20% (before the use of AF36) to 60% in 2002 following widespread utilization of AF36

For the reasons listed above we strongly recommend a timely approval of the registration process which would allow *Aspergillus flavus* AF36 to be used commercially throughout Arizona and Texas.

Very truly yours,

Fred Richard

Fred Richard
Manager



JFP

348 Soil and Crop Sciences • College Station, Texas 77843-2474 • (979) 845-2425 • FAX (979) 845-0604

April 1, 2003

Public Information and Records Integrity Branch (7502C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

RE: Docket ID Number OPP-2003-0048

This letter provides my support for registration of the microbial pesticide *Aspergillus flavus* AF36. AF36 is the first and only biological control method for eliminating aflatoxin contamination from cottonseed, and I strongly support the registration.

Texas annually harvests between four and five million bales of cotton. Due to environmental conditions, several production regions face perennial problems from aflatoxin contaminated cottonseed. These regions include central Texas (Blackland Prairie and Bottomlands) which produces about 230,000 bales, the south Texas region (Upper Gulf Coast and Coastal Bend) which generates over 700,000 bales, and the Rio Grande Valley area which generates over 200,000 bales. Together these areas support the production of over 1.1 million bales.

According to information provided by the "Office of the State Chemist", cottonseed from these three regions will generally test positive for aflatoxin, and between 15 to 80% of the cottonseed will exceed 20 ppb. As an example, in 1997 and 1998 over 80% of the cottonseed from these regions tested greater than 20 ppb, and in 2001 less than 15% exceeded 20 ppb. When aflatoxin levels in cottonseed exceed the 20 ppb limit, the value of the seed is severely discounted (in most cases by greater than 50%), translating into several million dollars lost to producers and the cottonseed industry. Moreover, due to extremely low prices for cotton lint in current and near-future markets, any discounts in cottonseed value further reduces profitability at the farm level.

Presently, there are no known means of reducing/eliminating aflatoxin contamination on any crop. The use of atoxigenic strains of *Aspergillus flavus* have proven to be very effective in combating aflatoxin problems in Arizona. Considerable cumulative acres have been treated in Arizona with no reported adverse effects. Multi-year air sampling studies have demonstrated that the atoxigenic strain AF36 has displaced the aflatoxin producing strains with no increase in total fungus in the environment.

Recent research conducted in the Coastal Bend region of Texas in 2000, 2001 and 2002 with the AF36 strain has also been very successful. Consequently, it is imperative that EPA grant permanent registration for *Aspergillus flavus* AF36 since this is the only means of eliminating aflatoxin problems in Texas cottonseed.

Based on previous research in Arizona and Texas, and the success of the area-wide program in Arizona, the granting of this registration for AF36 will serve as a major step in reducing aflatoxin problems in Texas cottonseed. I strongly support the registration for AF36 and urge the EPA to grant its approval.

Respectfully,

1/2

Robert G. Lemon
Associate Professor
and Extension Agronomist - Cotton
Department of Soil and Crop Sciences
Texas A&M University
College Station, Texas 77843-2474
r-lemon@tamu.edu

cc: Dr. Travis Miller
Dr. Mark Hussey
Dr. Peter Cotty
Dr. James Supak
Mr. Jeff Nunley

PP-2003-0048

(1F)

Arizona Department of Agriculture
1688 West Adams
Phoenix, Arizona 85007
Phone: (602) 542-0954 Fax: (602) 542-0466

March 21, 2003

Public Information and Records Integrity Branch
Office of Pesticide Programs
U. S. Environmental Protection Agency (7502C)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

ATTENTION: OPP-2003-0048

The purpose of this letter is to support the registration of *Aspergillus flavus* AF 36 for use on cotton to reduce populations of other strains of this fungus that produce aflatoxin. Aflatoxin contamination is a chronic problem in cotton grown in our low desert areas. We as a state agency need to administer a comprehensive monitoring program to protect animal feeds from contamination with this substance. While the contamination can be the result of post harvest handling of cottonseed, much of our aflatoxin problem can be traced to preharvest origins.

We feel that use of strain AF 36 as outlined in the experimental use permit 69224-EUP-1 significantly reduces the levels of aflatoxin present at harvest. Once introduced into an area, AF 36 maintains itself over several years, making reapplication unnecessary. This reduces grower costs, a timely bonus given the low prices currently paid for even premium quality cotton. This same attribute of AF36 makes it unlikely to attract the interest of commercial pesticide producers since a single treatment remains effective over so long a time period, limiting potential sales demand. Availability of AF 36 along with the other highly selective and effective pest control options such as genetically engineered cotton and insect growth regulators will enable our growers to produce superior quality cotton utilizing historically low volumes of pesticide.

Sincerely yours,

Edwin W. Minch

Edwin W. Minch
Environmental Specialist
Ed.minch@agric.state.az.us

(JPP)



1521 New Hampshire Avenue, NW • Washington, DC
(202) 745-7805 • FAX (202) 483-4040

PRODUCERS • GINNERS • WAREHOUSEMEN • MERCHANTS • CRUSHERS • COOPERATIVES • MANUFACT

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs (OPP)
Environmental protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001
opp-docket@epa.gov
Attention: Docket ID Number OPP-2003-0048

March 20, 2003

Re: Docket ID Number OPP-2003-0048; Comments on *Aspergillus flavus* AF-36
Registration Application (68 FR 11841; 3-12-03)

Dear Madam or Sir:

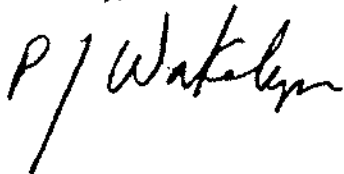
The National Cotton Council (NCC) supports this application from IR-4 (on behalf of The Arizona Cotton Research and Protection Council, Phoenix, AZ) to register the naturally occurring non-aflatoxin-producing microbial pesticide product *Aspergillus flavus* AF 36. NCC is the central trade association of the U.S. cotton industry, representing producers, ginners, oilseed crushers, merchants, cooperatives, warehouses, and textile manufacturers in 18 states. On average, NCC members produce and gin over 17 million bales of cotton and NCC cottonseed members handle over 6.5 million tons of cottonseed for oilseed processing and dairy feeding.

Full Section 3 registration for *A. flavus* AF-36 in both AZ and TX is very important to the economics of cotton production and reduction of toxigenic *Aspergillus flavus* and aflatoxin contamination of cottonseed in AZ and South TX. There are no other management techniques available that control toxigenic *A. flavus* contamination of cotton prior to harvesting. Post-harvest treatments (e.g., ammoniation) are not economical and have not obtained full regulatory approval from the U.S. Food and Drug Administration (FDA). This research using atoxigenic strains of *A. flavus* to displace aflatoxin-producing strains of *A. flavus* represents a scientifically valid biocontrol approach for reducing toxigenic *A. flavus* and aflatoxin contamination and also has great potential for other crops (e.g., corn, peanuts, pistachios, almonds, walnuts, and figs). This fungal material is already part of the naturally occurring microflora in the fields in AZ and South Texas and does not increase the amount of *A. flavus* in the field, so there are no unanticipated environmental or human affects.

Aflatoxin contamination of cottonseed causes significant economic losses (at least \$50/acre) to cotton producers, ginner, brokers, and oil mills in AZ and TX by reducing the value of this commodity (see J. Robens *The Cost of Mycotoxin Management to the USA: Management of Aflatoxins in the United States*, paper presented at Annual Meeting Am. Phytopath. Soc. Aug. 2001). Contamination of cottonseed and cottonseed meal severely restricts its use in feeding. If feed to dairy cattle, the aflatoxin can be metabolized and passed into the milk making the milk an adulterated product, according to the FDA.

NCC urges EPA to grant this petition to register the naturally occurring non-aflatoxin-producing microbial pesticide *Aspergillus flavus* AF 36. *Aspergillus flavus* AF 36 should be registered for use on commercial cotton fields in AZ and TX as soon as possible, so that this valuable research can be used this year. If there are questions please contact me at 202-745-7805 or by e-mail at pwakelyn@cotton.org.

Sincerely,



Phillip J. Wakelyn, Ph.D.
Senior Scientist, Environmental Health and Safety



Arizona Cotton
Growers Association

APR 11 2003

March 3/26/03

18

March 26, 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

RE: Docket ID Number OPP-2003-0048
***Aspergillus flavus* AF36 Registration Application (68 FR11841; 3-12-03)**

Dear Sir or Madam:

The Arizona Cotton Growers Association supports the application for full registration of *Aspergillus flavus* AF36 for use in Arizona and Texas. The Association has been deeply involved in the development and implementation of the technology on Arizona cotton since 1996. During this time the Association has observed the biological and economic benefits of AF36 treatments. Additionally, the Association has received no reports of adverse effects either from its grower community or the public at large under extensive experimental use conditions.

Full scale utilization of AF36 in both Texas and Arizona is very important to the reduction/elimination of aflatoxin contamination of cotton in these states, where significant economic losses to cotton farming have been reported since the 1960's. This research using non-toxic strains of *Aspergillus flavus* to displace aflatoxin-producing strains also has great potential for other crops such as corn and peanuts and is the only control mechanism of its kind nationwide.

The Arizona Cotton Growers Association urges EPA to grant full registration for *Aspergillus flavus* AF36 for use on commercial cotton fields in Arizona and Texas. If there are questions please contact me at (602) 437-1344.

Sincerely,

Rick Lavis
Executive Vice President

4139 E. Broadway / Phoenix, Arizona 85040 / (602) 437-1344
FAX (602) 437-5401



South Texas Cotton and Grain Association, Inc.

P.O. Box 4881 • Victoria, Texas 77903-4881 • Telephone: (361) 575-0631 • Fax: (361) 572-0960

March 31, 2003

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

APR 8 2003

POSTmarked 4/1/03

RE: Docket ID Number OPP-2003-0048

South Texas Cotton and Grain Association submits these comments to strongly support the application to register the naturally occurring non-aflatoxin-producing microbial pesticide *Aspergillus flavus* AF36.


South Texas Cotton and Grain Association is a trade association representing producer members who farm cotton and grain crops in the 33 counties in the Coastal Bend of South Texas. Cotton is a primary crop for our producers and cottonseed is a valuable byproduct of cotton production.

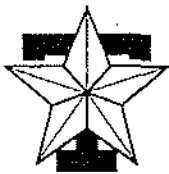
Aflatoxin is a perennial problem for farmers in South Texas and contamination of cottonseed costs producers millions of dollars each year in lost of value. Work done in Arizona has shown that applying atoxigenic strain AF36, which occurs naturally in fields, is effective in reducing the amount of aflatoxin in cottonseed by displacing toxin producing strains (especially the S-strain of *Aspergillus flavus*) without increasing the total amount of fungus in the environment.

Texas is similar to Arizona in that the atoxigenic strain AF36 occurs naturally in South Texas fields. Texas is also similar to Arizona in that the S-strain of *Aspergillus flavus* is the primary cause of aflatoxin contamination in cottonseed. Experiments in Texas using very small test plots have shown that applying *Aspergillus flavus* AF36 is effective in reducing the level of the S-strain.

Presently, there are no alternative methods available to producers to reduce aflatoxin producing fungi in cotton fields. Based on the success of an area-wide program in Arizona, as well as results from experiments in South Texas, the registration of *Aspergillus flavus* AF36 will provide a means for Texas cotton producers to reduce their economic losses from aflatoxin contamination of cottonseed. Our association strongly supports the application to register *Aspergillus flavus* AF36 and urges the EPA to grant its approval.

Sincerely,


Jeff Nunley
Executive Director



The Agriculture Program

THE TEXAS A&M UNIVERSITY SYSTEM • EXPERIMENT STATION

Feed and Fertilizer Control Service • Agricultural Analytical Services

P.O. Box 3160

College Station, Texas 77841-3160

Phone 979.845.1121 Fax 979.845.1389

Web: otscweb.tamu.edu

April 7, 2003

APR 10 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)

Office of Pesticide Programs (OPP)

Environmental Protection Agency

1200 Pennsylvania Ave., NW

Washington, DC 20460

Attn: Docket ID Number OPP-2003-0048

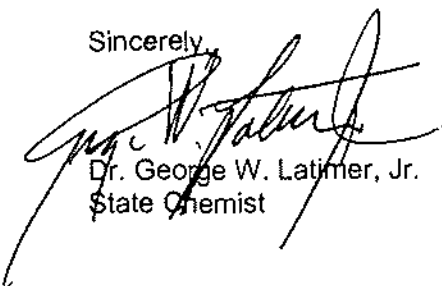
To Whom It May Concern:

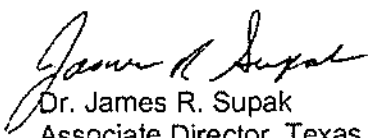
The Office of the Texas State Chemist has the responsibility for ensuring that grains and oilseeds used in animal feed meet federal and state standards for levels of aflatoxin. Despite the cooperative effort of farm organizations, the industry and this Office to minimize the effect of aflatoxin contamination in feed ingredients over the last 14 years, there has still been severe economic loss from infestations of *A. flavus*. Currently the only method for preventing or minimizing aflatoxin contamination of cottonseed or other grains and oilseeds is ammoniation; the proposed procedure – a biological control – does not require the use of synthetic chemicals.

This Office strongly supports the application for **Registration of the Microbial Pesticide *Aspergillus flavus* AF36** to reduce aflatoxin contamination of cottonseed. Commercial use of this biological control agent developed from the non-toxin-producing, naturally occurring strain (AF-36) could greatly benefit animal and human health, increase food safety and reduce economic losses to producers, processors and end users associated with aflatoxin contamination of cottonseed. It would also reduce the regulatory burden the State of Texas must now assume to ensure proper disposition of aflatoxin-contaminated grains and oilseeds.

Our Office monitors both feed ingredients and manufactured feeds for all types of domestic livestock. The control of aflatoxin in raw feedstuffs is an important part of our state-federal-industry feed quality and safety partnership. While the presence of aflatoxin varies by years and locations, the levels of this contamination are of particular concern in the southern and central regions of Texas. AF-36 would be the first commercially available product with potential to reduce aflatoxin contamination of cottonseed in Texas and Arizona.

Sincerely,


Dr. George W. Latimer, Jr.
State Chemist


Dr. James R. Supak
Associate Director, Texas
Agricultural Experiment Station

cc: Dr. Peter Cotty
Mr. Jeff Nunley
Dr. Charles Scifres
Dr. Frank Gilstrap

OPP-2003-0020 Docket Index

Legacy Identifier: OPP-2002-0093

Title: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

Displaying 1- 18 of 18 Documents Found

<u>Document ID</u>	<u>Date</u>	<u>Type</u>	<u>Title</u>
OPP-2003-0020-0001	02-14-2003	Federal Register	Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0002	05-26-1999	Support-Background	Aspergillus Flavus AF36; Pesticides Tolerance Exemption
OPP-2003-0020-0003	05-23-2001	Support-Background	Aspergillus Flavus Af36; Extension of Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0020-0004	07-17-2002	Support-Background	Aspergillus Flavus Af36; Amendment, Temporary exemption from the Requirement of a Tolerance
OPP-2003-0020-0005	12-23-2002	Support-Background	Aspergillus AF36 ai#006456; Pending Section 3 Registration Number 71693-R, Petition 8E5001
OPP-2003-0020-0006	02-19-2003	Public Comment	Comments from a Private Citizen Re:Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0007	03-07-2003	Public Comment	Comments from the Farmers Gin, Inc. Re: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0008	03-03-2003	Public Comment	Comments from the Anderson Clayton Corp. Re: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0009	03-03-2003	Public Comment	Comments from the Texas A&M University Agricultural Research & Extension Center Re: Aspergillus flavus AF36
OPP-2003-0020-0010	03-07-2003	Public Comment	Comments From the Texas Cooperative Extension (Texas A&M Univ.) Re: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0011	03-13-2003	Public Comment	Comments From The South Texas Cotton and Grain Assoc. Re: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0012	03-10-2003	Public Comment	Comments From The Arizona Cotton Growers Assoc. Re: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
			Comments from the Arizona Dept. of Agriculture

OPP-2003-0020-0013 03-14-2003 Public Comment

Re: *Aspergillus flavus* AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

OPP-2003-0020-0014 03-14-2003 Public Comment

Comments from the National Cotton Council Re: *Aspergillus flavus* AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

OPP-2003-0020-0015 Public Comment

Comments from the SRS Farms Re: *Aspergillus flavus* AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

OPP-2003-0020-0016 03-13-2003 Public Comment

Comments from the Yuco Gin, Inc. II Re: *Aspergillus flavus* AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

OPP-2003-0020-0017 Public Comment

Comments from the Grower's Mohawk Gin, Inc. Re: *Aspergillus flavus* AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

OPP-2003-0020-0018 03-13-2003 Public Comment

Comments from the Chandler Ginning Co. Re: *Aspergillus flavus* AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food



F. J.

OPP-03-0048



Chandler Ginning Co.

(1P)

MAILING ADDRESS: P. O. Box 3120 Casa Grande, AZ 85222-0120
Phone & Fax (520) 723-4934

A Grower Owned Ginning Association

March 26, 2003

APR - 1 2003

LOCATION

5878 North
Eleven Mile Corner Rd

GENERAL MGR:

Gale
Extension # 11

GIN MGR:

Kim Vale
Extension # 12

OFFICE MGR:

Ginny Hoefar
Extension # 10

BOOKKEEPER:

Mike Strong
Extension # 13

BOARD OF DIRECTORS:

President:
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Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency,
1200 Pennsylvania Ave., NW,
Washington, DC 20460-0001

Paceknow 3/27/03

RE: Docket ID Number OPP-2003-0048; *Aspergillus flavus* AF36
Registration Application (68 FR11841; 3-12-03)

Dear Sir or Madam:

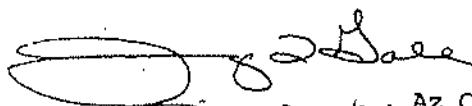
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Several member gins of our Association have experienced very positive results as a result of AF36 use by the growers. For this and the other reasons listed above we strongly recommend a timely approval of the registration process which would allow *Aspergillus flavus* AF36 to be used commercially throughout Arizona and Texas.

Very truly yours,



President, Az Cotton

181
293

11

01-11 0070

FARMER'S GIN, INC.

3825 S. 99TH AVE • TOLLESON, ARIZONA 85383 • OFFICE: (623) 936-8505 • GIN: (623) 386-2020 OR (623) 386-5899

March 26, 2003

(1P)

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

APR - 1 2003

Postmarked 3/26/03

Re: Docket ID Number OPP-2003-0048; *Aspergillus flavus* AF36 Registration
Application (68-FR11841;3-12-03)

Dear Sir or Madam:

This letter is my written comment on the application for registration of *Aspergillus flavus* AF36 for the prevention of aflatoxin contamination of cottonseed in Arizona.

I am a cotton farmer and the President of Farmer's Gin, Inc. Historically, over 50 percent of the cottonseed produced at our gin has tested higher than 20 ppb of aflatoxin. The majority of our 12,000 ton annual production goes to the dairy feed market. I estimate our losses at \$100,000 per year due to the higher levels.

High levels of aflatoxin are a serious problem in Arizona. The high levels reduced the value of the seed and place the seller at risk legally if subsequent tests show higher levels of contamination than that certified at the time of the sale. Several lawsuits and state regulatory administrative actions have occurred in recent years pitting dairymen and regulators against seed brokers, gins and cotton farmers.

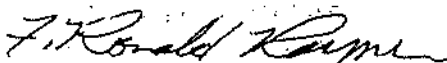
There are no products currently on the market that will reduce or prevent aflatoxin contamination in any crop. There are also no cultural practices or biological controls that help reduce the levels.

The registration of *Aspergillus flavus* AF36 will be the first product available for reducing aflatoxin contamination of cottonseed. This product is needed by the industry in Arizona and in Texas as well.

I am pleased to hear that the product is not a synthetic chemical, but a naturally occurring strain of *Aspergillus* that does not produce aflatoxin and replaces the strains that do.

I strongly support the registration of AF36.

Sincerely,


F. Ronald Rayner, President



Anderson Clayton Corp.

2226 W. NORTHERN AVE., SUITE C201 • PHOENIX, AZ 85021

PHONE (602) 841-2111 • FAX (602) 841-2444

(1P)

March 27, 2003

APR - 1 2003

Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Received 3/27/03

RE: Docket ID Number OPP-2003-0048; *Aspergillus flavus* AF36 Registration Application
(68 FR11841; 3-12-03)

Dear Sir or Madam:

The Anderson Clayton Corporation is writing to support the registration of *Aspergillus flavus* AF36 for the control of aflatoxin in Arizona cottonseed.

Our company conducts extensive cottonseed ginning and sales operations in Arizona where aflatoxin contamination has plagued growers for more than 30 years. This contamination has resulted in lost revenue and profit to Anderson Clayton, its raw material suppliers (cotton producers) and cottonseed feeders (primarily dairies) and cottonseed products consumers (again, primarily dairy, but other food consumers as well).

The extraordinary fluctuations of aflatoxin contamination have resulted in losses for Arizona cotton producers in the millions of dollars.

It is our experience that no products are approved or even currently exist for treatment of any crop to prevent aflatoxin contamination in the field. *Aspergillus flavus* AF36, a biological control using no synthetic chemicals, is the first product available for reducing such contamination in cottonseed.

As a company that has directly and indirectly been affected by aflatoxin contamination of cottonseed, we have long tracked and supported the USDA ARS work conducted by Dr. Peter Cotty on aflatoxin in cottonseed and other agricultural commodities. Having seen first hand the negative financial exposure and impact aflatoxin contamination can have on our customers as well as our company, we strongly urge registration of *Aspergillus flavus* AF36 on cotton in Arizona and Texas.

Sincerely,

Jeffery J. Ballentine
V. P. Arizona Operations

Attached You Will Find an Updated Index for Your Docket:

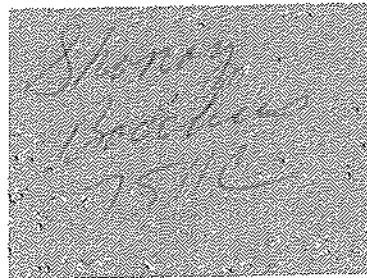
Docket # <i>OPP03-0020</i>	Date Index Sent: <i>APR - 4 2003</i>
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Docket # <i>OPP-2003-0048</i>	Date Index Sent: <i>APR - 4, 2003</i>
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OPP-2003-0048 Docket Index

Legacy Identifier: OPP-2003-0020

Title: Pesticide Product; Registration Application

Displaying 1- 10 of 10 Documents Found

<u>Document ID</u>	<u>Date</u>	<u>Type</u>	<u>Title</u>
OPP-2003-0048-0001	03-12-2003	Federal Register	Pesticide Product; Registration Application
OPP-2003-0048-0002	05-26-1999	Support-Background	Aspergillus Flavus Af36; Pesticide Tolerance Exemption
OPP-2003-0048-0003	05-23-2001	Support-Background	Aspergillus Flavus Af36; Extension of Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0048-0004	07-17-2002	Support-Background	Aspergillus Flavus Af36; Amendment, Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0048-0005	12-23-2002	Support-Background	Aspergillus Flavus AF36 ai#006456 Pending Section 3 Registration Number 71693-R, Petition 8E5001
OPP-2003-0048-0006	02-14-2003	Support-Background	Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0048-0007	03-26-2003	Public Comment	Comments from the Chandler Ginning Co. Re: Pesticide Product; Registration Application
OPP-2003-0048-0008	03-26-2003	Public Comment	Comments from the Farmer's Gin, Inc. Re: Pesticide Product; Registration Application
OPP-2003-0048-0009	03-27-2003	Public Comment	Comments from the Anderson Clayton Corp. Re: Pesticide Product; Registration Application
OPP-2003-0048-0010			Comments from the Grower's Mohawk Gin, Inc. Re:



Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

06/16/03 09:51 AM

To: Peter Cotty <picotty@srrc.ars.usda.gov>, Shanaz
Bacchus/DC/USEPA/US@EPA

cc: [REDACTED]

Subject: RE: AF36/cottonseed meal/cottonseed oil

Shanaz

In relation to questions A and B below...

A. See MRID 43763403 page 624 which is from a journal article: Influence of Field Application of an atoxigenic strain of *A. flavus* on the populations of *A. flavus* infecting cotton bolls and on the aflatoxin content of cottonseed.

There is no change in the total population of *A. flavus* compare to the control due to treatment with AF36 only the composition. In addition direct feeding in mamalian acute oral studies showed no adverse affect.

Furthermore, the fungus is killed during oil extraction with organic solvent such as hexane, the leftover part is the cottonseed meal

B. This is what constitutes efficacy. There is no increase in aflatoxin due to treatment with AF36, there is a decrease. See the same article cited above. Aflatoxin is not oil soluble and thats why it stays with the meal.

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Sunday, June 15, 2003 12:16 PM
To: Mike Braverman
Subject: RE: AF36/cottonseed meal/cottonseed oil

Please bear with me, because I have not looked at the data submissions and I'm looking for hard data which may be already available.
Does Peter have any data to show that:

a. AF36, the fungus (hyphae, mycelia, conidia, etc.,) is not found in cottonseed meal and cottonseed oil? Or if there are data to show that *Aspergillus* is normally found in these food commodities, do they show that the levels of *Aspergillus* found in the controls are not any greater than those treated?

b. aflatoxin levels in these food commodities (cottonseed meal and cottonseed oil) do not change above background aflatoxin levels as a result of treatment with AF36?

I am preparing the final documents for Janet to send up to Jim Jones for

signature. It may a tight call to give you final word from JJones on Wed. since I plan on putting the whole package on Janet's desk on Tues a.m. However, this week is it. As you can see, I'm working on it today, Sunday, proofing, editing, finalizing. You will get a chance to look at the BRAD before it goes on the Web.

Please call me at home (301-924-7114) where I'll be working on Monday morning.

Thanks for your patience and for answering all these nagging questions.

Sincerely,

Shanaz Bacchus, Chemist/RAL

BPPD/OPP

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0138; FRL-7311-6]

Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial antifungal agent *Aspergillus flavus* AF36, a non-aflatoxin-producing member of the naturally-occurring genus of fungi *Aspergillus*, in or on the food/feed commodity cotton when the pesticide is used according to its label instructions as a prebloom application. The Interregional Research Project Number 4 (IR-4), on behalf of the Arizona Cotton Research and Protection Council, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

DATES: This regulation is effective [insert date of publication in the Federal Register]. Objections and requests for hearings, identified by docket ID number OPP-2003-0138, must be received on or before [insert date 60 days after date of publication in the Federal Register].

ADDRESSES: Written objections and hearing requests may be submitted by mail or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: bacchus.shanaz@epa.gov.

CONFERENCE							
SYMBOL	7104T	7104T	7511C	7511C	7511C	7511C	7511C
SURNAME	E. Blom	J. P. Blom	Bacchus	Konietzke	Appel	Szuchay	Horton
DATE	5-30-2003	5/30/2003	6/3/2003	6/4/2003	6/16/03	6-18-03	6/19/03

EPA (OPP) 15263 (112-70)

with comments
with comments
with comments

OFFICIAL FILE COPY

25 6-3-03

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

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OPP-354				CONFIDENTIAL			
SYMBOL	7104T	7104T	7511C	511C			
SURNAME	E. Hines	J. P. Hines	K. Hines	C. Hines			
DATE	5-30-2003	5/30/2003	6-4-03	6-05-03			

W/minutes n/minutes

Attachment #2: OPPTS Docket Verification and Certification Form



U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
(OPPTS)

1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action: *Final Rule: Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance*

RIN #: 2070-

Docket ID #: *OPP-2003-0138*

FRL#:

Contact Information:

Name: *Shanez Bacchus*

Phone: *703-308-8097*

Legacy Information:

OPP2003-0048, OPP2003-0020

Program Lead's Verification: I have reviewed the docket and verified the following:

- ☐ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- ☐ Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.
- ☐ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.

☒ Comments: *no support document*

Date:

4/2/03

Initials:

Shanez Bacchus

Phone:

703-308-8097

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- ☐ The Docket ID # identified above matches our records.
- ☐ The documents identified in the attached Docket Index have been received by the Docket.
- ☐ The documents have been properly processed for inclusion in EPA Dockets, as appropriate.
- ☐ The documents either already are in the docket or are being process for inclusion in the docket.

☒ Comments: *NO Support + DOC.*

Date:

4-2-03

Signature:

[Signature]

Phone:

305-6434

Program Lead's Certification: I hereby certify that:

- ☐ I have completed the verification above.
- ☐ I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.
- ☐ I have obtained the DM's sign-off.
- ☐ The docket is complete and ready for public release.

☒ Comments: *No support doc*

Date:

4/2/03

Signature:

Shanez Bacchus

Phone:

703-308-8097

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0138; FRL-7311-6]

Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0138. The official public docket is intended to serve as a repository for materials (i.e., documents and other information) submitted to the Agency in connection with this action and/or relied upon by the Agency in taking this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. To the extent that a particular document is not located in the official public docket, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

The legacy docket for this case is OPP-2003-0020, which was set up in connection with the Notice of Filing of this pesticide petition, 8E5001. It contains the **Federal Register** Notice dated February 14, 2003, (68 FR 7554), which was published to announce this petition, other relevant **Federal Register** documents associated with the exemption from temporary tolerance which preceded this permanent exemption from tolerance, and comments received in response to the publication of this petition.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a

beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of February 14, 2003 (68 FR 7554) (FRL-7289-9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 8E5001) by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, ~~Technology Center of New Jersey~~, Technology Center of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390, on behalf of the Arizona Cotton Research and Protection Council, 3721 East ~~West~~ ^{Wier} Avenue, Phoenix, AZ 85040-2933. [only once for Tech Center - (Wier)] This notice included a summary of the petition prepared by the petitioner, IR-4, on behalf of the Arizona Cotton Research and Protection Council. In response to the notice of filing of this petition, comments in favor of the use of the pesticide were received from cotton growers, processors and ginnerers, mainly from Arizona and Texas.

The petition requested that 40 CFR 180.1206 be amended by establishing an exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider "available information" concerning the cumulative

effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Aspergillus flavus AF36 (also referred to as AF36 or ~~L-strain~~) is a non-aflatoxin-producing or atoxigenic strain of *Aspergillus flavus*, whose species are ubiquitous around the world. Some members of the genus *Aspergillus* produce mycotoxins, such as aflatoxin, a potent carcinogen produced by toxigenic strains of *A. flavus*. Other members of the genus *Aspergillus* have been domesticated for commercial use, such as *Aspergillus niger* for production of enzymes (e.g., alpha-galactosidase found in *Beano*, a dietary supplement) and *Aspergillus oryzae* for production of soy sauce. The subject strain of this final rule, *Aspergillus flavus* AF36, is characterized as an atoxigenic strain by its lack of production of aflatoxin. It is not vegetatively compatible with the toxigenic strains of *A. flavus*, a feature which limits cross-over potential to, and, thus, further proliferation of, the toxigenic strains. Starter cultures, selected on the basis of the vegetative incompatibility with aflatoxin-producing strains, are to be monitored by standard thin layer chromatography (TLC) procedures, and visualization via scanning fluorescence densitometry scanning [Master Record Identification Number (MRID) 44626101; BPPD Data Evaluation Report of Analysis of Samples, dated March 29, 1999 (hereinafter referred to as "BPPD review - March 29, 1999"); BPPD Review of Supplementary Information dated May 14, 1999 (hereinafter referred to as "BPPD review - May 14, 1999")]. In this manner, the applicant proposes to maintain batches free of aflatoxin contamination during production. Batches contaminated with aflatoxin, or human pathogens, or unintentional ingredients above regulatory levels are to be destroyed. Thus, use of AF36 is not likely to add to the environmental burden of the aflatoxin-producing strains of *A. flavus*.

The pesticide is proposed for a single prebloom application once a year to cotton fields to displace the aflatoxin-producing strains of *Aspergillus flavus* from cotton. Sterilized wheat seeds, colonized with *Aspergillus flavus* AF36, are to be applied at 10 lb of end-use product

(EP) (equivalent to the low rate of less than 0.01 lb active ingredient (ai) per acre). Within 3 days of application of the pesticide, the fields are furrow irrigated to promote germination of AF36, which colonizes the cotton crop and soil, before the aflatoxin-producing strains of *A. flavus* proliferate. This competitive exclusion of the aflatoxin-producing strains does not increase the total *Aspergillus* population in the environment above background levels as demonstrated in soil and air monitoring studies. [MRIDs 45307201, 45307202; BPPD Review of Soil and Air Monitoring Studies and Product Performance Testing (Efficacy), dated May 15, 2003 (hereinafter referred to as "BPPD Review - May 15, 2003")]. The displacement of the toxigenic strain of *Aspergillus flavus* by AF36 may reduce aflatoxin contamination of cotton seed. → apparently

The toxicology and pathogenicity data generated by the petitioner in support of this tolerance exemption, and reviewed by the Agency, are summarized below. The following discussion of the evaluations of the submitted studies and information indicates that exposure to the pesticide is not likely to be greater than that which occurs normally to other ubiquitous *A. flavus* strains. Submitted data also indicate no toxicity or infectivity of AF36 in test mammalian systems. More detailed analyses of these studies can be found in the specific Agency reviews of the studies that are cited below.

1. *Acute oral toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3050; MRID 43972403)*. Agency evaluation of submitted acute oral study indicates no toxicity/infectivity effects of the pesticide. Five male, and five female Sprague Dawley rats were treated orally with the microbial pesticide (500 milligrams/milliliter (mg/mL) or 6.3×10^3 cfu/mL) by gavage. No clinical signs or abnormalities were noted during the study, and the pesticide was considered to be neither toxic nor infective following oral administration of a single dose. The acute oral test resulted in a Toxicity Category IV classification with a lethal dose (LD)₅₀ greater than 5,000 milligrams/kilogram (mg/kg) body weight [MRID 43972403; BPPD Data Evaluation Report, Acute Oral Toxicity Study in Rats, dated April 23, 1996 (hereinafter referred to as "BPPD Review - April 23, 1996")].

2. *Acute pulmonary toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3150; MRID 45798201)*. The Agency required an intratracheal pulmonary infectivity/pathogenicity study. This test involves intratracheal instillation of the test material and post mortem examination of lungs and other organs for clearance.

Three studies were submitted in support of the mammalian acute infectivity/pathogenicity pulmonary guideline: A range finding study and two complete acute pulmonary studies. The dose-range study concluded that 10^8 cfu/rat would be a suitable test dose level for the acute pulmonary studies [MRID 45739101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as "BPPD Review - April 02, 2003a")]. In the first acute pulmonary study, conducted with

Tween 80 as a surfactant in the test material, 26 male and 26 female Sprague Dawley rats (approximately 8 to 10 weeks old) each were dosed with a single intratracheal dose of 1.2 mL/kg at 5.30×10^8 cfu/mL (or 1.28 to 1.63×10^8 cfu/animal). Results from this study indicated that the test organism was neither infective nor pathogenic, in spite of rat mortality, which is believed to have been due to a severe acute inflammatory response to the Tween 80 [MRID 45798101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as "BPPD Review - April 02, 2003b")].

In the second acute pulmonary study, which was a repetition of the first acute pulmonary test, but was conducted without Tween 80, 25 male and 25 female Sprague Dawley rats (approximately 8 to 10 weeks old) each received a single intratracheal dose of approximately 1.2 mL/kg. Mortality of 4 rats by day 2 appeared to be attributable to an initial dosing effect. The rest of the test animals showed an initial response, followed by a rapid recovery indicating no toxicity. Although some surviving rats lost weight intermittently, all surviving rats gained weight prior to scheduled sacrifice. No clinical signs that were considered to be due to the test organism were observed in the test rats. Organs were examined *post mortem* as previously described. *Aspergillus flavus* AF36 was detected in the lungs with clearance by day 8 after dosing. No test organisms were detected in any samples from the shelf control or inactivated test organism treated rats. Based on the presented/submitted data, including the clearance data, the test organism, *Aspergillus flavus* AF36, was considered not toxic, infective, or pathogenic to the rat pulmonary system. The study is acceptable.

3. *Acute inhalation (OPPTS Harmonized Guideline 152-32)*. The inert is sterilized wheat seeds, comprising approximately 99% of this pesticidal product. It acts as a matrix and nutrient source for the germinating AF36. Because this constitutes ~~more than 20%~~ ^{majority of the} of the pesticide and does not contain respirable particles of less than 10 microns, an inhalation study was not required pursuant to 40 CFR 158.740(c). In addition, based on the results obtained through the acute pulmonary toxicity/pathogenicity studies summarized immediately above, AF36 is considered not toxic, infective, or pathogenic to the rat pulmonary system. On the basis of this study and the nature of the inert ingredients present, the pesticide was considered Toxicity Category III for acute ~~pulmonary~~ ^{inhalation} effects. [MRID 45798201; BPPD Data Evaluation Report, dated April 02, 2003c (hereinafter referred to as "BPPD Review - April 02, 2003c")].

4. *Hypersensitivity incidents (OPPTS Harmonized Guideline 152-37; MRID 45739104)*. The registrant submitted information (MRID 45739104) to demonstrate the lack of hypersensitivity to workers who have been exposed during the manufacture, application, and use of the pesticide in the research and experimental phases. No adverse hypersensitivity reaction to AF36 was recorded ^{reported} by a state council or six companies during use for 3 or 6 years [MRID 45739104; ✓ (or)]

BPPD Data Evaluation Report, dated April 02, 2003d (hereinafter referred to as "BPPD Review - April 02, 2003d"). However, to comply with the Agency's requirements under section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

5. *Data waivers.* Data waivers were requested for the following studies:

- i. Acute dermal toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3100)
- ii. Primary dermal irritation (OPPTS Harmonized Guideline 870.2500)
- iii. Primary eye irritation (OPPTS Harmonized Guideline 870.2400)
- iv. Intravenous, intracerebral, intraperitoneal injection (OPPTS Harmonized Guideline 885.3200)
- v. Hypersensitivity study (40 CFR 152-36)
- vi. Immune response (40 CFR 152-38)

With regards to the dermal and eye irritation guideline tests, it was impractical to apply the end-use product, sterilized wheat seeds inoculated with *Aspergillus flavus* AF36, as test material. Furthermore, non-occupational dermal and eye exposures, or exposures via any of the routes in Unit III.5.i.—vi., are not likely to be above naturally-occurring background levels for the following reasons.

First, *Aspergillus flavus*, a saprophytic fungus, is a normal constituent of the microflora in air and soil. The naturally occurring soil and plant colonizer is also found on living and dead plant material throughout the world. Aflatoxin-producing strains of *Aspergillus flavus* are particularly prominent in hot, dry climates supplemented with irrigation and are ubiquitous components of the natural Arizona desert ecosystem. Quantities of *A. flavus* typically increase during crop production and the fungus occurs widely on crop debris left in the soil. Shortly after application, AF36 germinates, displaces the aflatoxin-producing strains from cotton and the soil, and spore levels return to normal background, without increase of total *A. flavus*. This was demonstrated in soil and air monitoring studies submitted over multiple years of experimental usage [BPPD Review - May 15, 2003]. Thus exposures to AF36 are not likely to increase above those normally associated with the naturally occurring *A. flavus* background levels. *apparently*

Second, the application rate is low, being less than 0.01 lb active ingredient per acre, and agricultural sites are treated, thus minimizing non-occupational and residential exposure. The proposed label rate is less than 0.01 pound of active ingredient in 10 pounds end-use product, or approximately 1.34×10^7 colony forming units (cfu) per acre.

Finally, ~~spray~~ drift is not expected during application based on the large granular nature of the pesticide (i.e., sterilized inoculated wheat seeds). In addition, only one prebloom application is made, and cultivation is not recommended after application. Thus, once again, the potential for non-occupational dermal and residential exposure is unlikely.

The acute oral toxicological study demonstrated an LD₅₀ of greater than 5,000 mg/kg with no toxicity/infectivity effects, and demonstrable clearance from organs examined *post mortem* [MRID 43972403; BPPD Review - April 23, 1996]. This rationale supported the request to waive the acute intraperitoneal study.

A hypersensitivity study was waived since hypersensitivity incidents were not reported from maximally exposed workers and researchers during the research and experimental phases associated with the use of the active ingredient, *A. flavus* AF36 [BPPD Review - April 02, 2003d]. Nevertheless, reports of hypersensitivity incidents associated with the use of the pesticide are still required to comply with FIFRA section 6(a)(2) requirements.

Submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) also indicate that following oral and pulmonary routes of exposure [BPPD Review - April 23, 1996; BPPD Review - April 02, 2003c], the immune system is still intact and able to process and clear the active ingredient. Thus, the request to waive the immune response study was granted.

On the basis of the foregoing rationales, and there being no documented problems associated with the non-aflatoxin producing strain, *Aspergillus flavus* AF36, data waivers for the studies listed in Unit III.5.i.—vi., were granted to the applicant for the proposed use of *Aspergillus flavus* AF36 on cotton.

6. *Subchronic, chronic toxicity and oncogenicity, and residue.* Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is a potential for aggregate exposure of adult humans, infants and children to the microbe because of the ubiquitous distribution of *Aspergillus* fungal strains in the environment. The Agency has considered the incremental exposure and risk associated with the proposed application of this strain of *Aspergillus flavus*, AF36, as summarized below, and concludes that use of AF36 is not likely to add an incremental risk above that posed by the normal exposure of adults, infants and children to *Aspergillus flavus* strains present in the environment. In fact, use of the pesticide, AF36, may decrease potential environmental aflatoxin exposure to exposed populations.

A. Dietary Exposure

1. *Food.* Based on submitted studies, the end-use product, *Aspergillus flavus* AF36, demonstrates low acute oral toxicity category IV potential [BPPD Review - April 23, 1996]. No toxicity endpoints were indicated to justify setting a numerical tolerance for the fungal active ingredient, *Aspergillus flavus* AF36. An LD₅₀ greater than 5,000 mg/kg body weight, in the acute oral studies discussed above, indicates that consumption of food commodities treated with AF36 poses no incremental risk via dietary exposure. Indeed, the submitted data indicate no toxicity or infectivity of AF36 in the acute oral test mammalian systems.

Cotton itself is not a food commodity. Residues of *A. flavus* AF36, the microbial active ingredient, are not likely to survive the heating and pressure associated with the processing of cottonseed into cottonseed meal. Moreover, *A. flavus* AF36 will not separate into the edible fraction, cotton seed oil. Thus, potential transfer of residues of *A. flavus* AF36 to edible cotton food/feed commodities is not expected. Consequently, human dietary exposure to *A. flavus* AF36 via cottonseed oil, or by secondary transfer of *A. flavus* AF36 residues to meat and milk via cottonseed meal, is not expected. Therefore, the Agency has determined that dietary exposure to *A. flavus* AF36 is not likely to result in any undue health effects and risk.

While the Agency has concluded that AF36 is not likely to add to the dietary burden, any potential contribution by AF36 to aflatoxin contamination was also considered, for a conservative estimate of the health effects of this pesticide. This is because aflatoxin is considered a public health hazard (see Unit VII.D.) and AF36 is proposed as a biocontrol agent for aflatoxin-producing strains of *A. flavus*. Even if AF36 does not control aflatoxin levels in the treated cotton food/feed commodities, a safety net exists in the screening of cotton and its by-products for aflatoxin prior to their introduction into the channels of commerce. For instance, FDA does not allow cotton seed products containing aflatoxin above 20 parts per billion (ppb) to be used in dairy rations or above 300 ppb to be used for feeding beef cattle. As previously stated, the registrant claims that quality control and selection procedures will not allow aflatoxin production in the starter cultures

for pesticide manufacture [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Any batches with aflatoxin are to be destroyed. For these reasons, the Agency has determined that use of AF36 will not add to the dietary burden of aflatoxin, but is rather more likely to ameliorate aflatoxin levels in treated cotton food/feed commodities. Therefore, dietary exposure to aflatoxin, as a result of AF36 use, is not likely to be greater, and may even be less, than that which currently exists.

2. *Drinking water exposure.* Exposure to AF36 via drinking water is not likely to be greater than current/existing exposures to *A. flavus* strains. Potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, percolation through soil. Thus, exposure via drinking water from the proposed use of this non-aflatoxin-producing strain of *Aspergillus flavus* is not likely to pose any incremental risk to adult humans, infants and children. In fact, displacement of the toxigenic strains of *A. flavus* by AF36 may decrease exposure and risk to the toxigenic strains of *A. flavus* in the environment, ~~and in water.~~ ✓

B. Other Non-Occupational Exposure

1. *Dermal exposure.* The potential for non-occupational dermal exposure to AF36 is unlikely because the potential use sites, are commercial and agricultural, and because of the granular nature of the pesticide, which minimizes spray drift. As discussed earlier (see Unit III.), lack of hypersensitivity incidents, low application rates, and return of levels of *Aspergillus flavus* to background shortly after germination, poses minimal risk to populations via dermal, non-occupational exposure. Thus, dermal non-occupational exposure to the non-aflatoxin strain is not likely to be greater than the existing exposure to *A. flavus* at current levels.

2. *Inhalation exposure.* For the reasons stated immediately above, non-occupational inhalation exposure to AF36 is not expected to be greater than that which currently exists for *A. flavus* strains.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *Aspergillus flavus* AF36 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *Aspergillus flavus* AF36 does not appear to be toxic or pathogenic to humans. Thus, there is no indication that the fungus *A. flavus* AF36 shares any common mechanisms of toxicity (metabolic mechanisms) with other substances. In addition, there are no other registered products containing *Aspergillus flavus* AF36, and other *A. flavus* strains abound naturally in the environment. Moreover, the displacement of the toxigenic strain of *A. flavus* by AF36 may reduce aflatoxin contamination of cottonseed. Based on the low

✓ registered pesticides

toxicity potential of AF36, the fact that it is non-aflatoxigenic, and the safety net already in place to monitor for aflatoxin, no cumulative or incremental effect is expected from the use of AF36 on cotton.

VI. Determination of Safety for U.S. Population, Infants and Children

There is reasonable certainty that no harm will result from aggregate exposures to residues of *A. flavus* AF36, in its use as an antifungal agent, to the U. S. population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm, from this fungus in its use as an antifungal agent via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects (~~Toxicity Categories IV and III, respectively~~), with no toxicity or infectivity at the doses tested (see Unit III above). Moreover, non-occupational inhalation or dermal exposure is not expected above background levels (see Unit V).

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that the fungus, *A. flavus* AF36, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when *A. flavus* AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *A. flavus* AF36.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority, to require the wildlife evaluations. As the

science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of this active ingredient, *Aspergillus flavus* AF36, at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this microorganism. The submitted toxicity/infectivity or pathogenicity studies in the rodent (required for microbial pesticides) indicate that, following oral and pulmonary routes of exposure, the immune system is still intact and able to process and clear the active ingredient (see Unit III.). In addition, based on the low potential exposure level associated with the proposed single, seasonal, prebloom application of the pesticide, the Agency expects no adverse effects to the endocrine or immune systems.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Accordingly, the Agency has concluded that for an exemption from tolerance, analytical methods are not needed for enforcement purposes for residues of *Aspergillus flavus* AF36 on treated cotton. Nonetheless, and for purposes of clarification, analytical methods are still required for product characterization, quality control, and quality assurance for manufacturing purposes [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Vegetative compatibility tests are used to screen starter cultures to identify the non-aflatoxin-producing *Aspergillus flavus* AF36 strain. Starter cultures of AF36 are also selected on the basis of the lack of aflatoxin as monitored by standard thin layer chromatography (tlc) procedures and visualization via scanning fluorescence densitometry scanning. Other appropriate methods are required for quality control to assure product characterization, the control of human pathogens and other unintentional metabolites or ingredients within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

C. Codex Maximum Residue Level

There is no Codex maximum residue level for residues of *Aspergillus flavus* AF36.

D. Efficacy Data

PR Notice 2002-1 lists aflatoxin as a public health hazard, for which product performance or efficacy data are required according to 40 CFR 158.202(i). To demonstrate that this pesticide may reduce aflatoxin-producing strains and does not increase *A. flavus* populations above

background levels, the applicant provided product performance or efficacy data from multiple years of soil and air monitoring studies.

Aflatoxin, one of the most potent human carcinogens, is the metabolite of concern produced by the target pest, aflatoxin-producing strains of *Aspergillus flavus*. As such, the Agency considers aflatoxin a public health hazard. In the soils of cotton-producing areas of Arizona and south Texas, especially in the dry regions, the toxigenic strains are prominent. Few alternatives, if any, exist to displace aflatoxin-producing *A. flavus* strains from cotton and other crops. Decontamination of crops via ammoniation is costly, not available universally, and decreases the value of the crop. Other methods to reduce aflatoxin formation include manipulation of harvest date, costly irrigation practices, and different methods of harvesting and storage practices. ✓

Efficacy data submitted to the Agency include monitoring of soil and air levels of the toxigenic and non-aflatoxin-producing strains of *A. flavus* AF36 in the field and on the crops. Results from the environmental expression and population monitoring studies during the experimental program, demonstrate that a ^{single} ~~one time~~ seasonal application of AF36 on cotton fields may incite significant changes in the incidence of toxigenic *A. flavus* strains resident in the agroecosystem, without altering the overall quantity of *A. flavus*. Soil and air population counts of *A. flavus* from treated fields were associated with concomitant decreases in incidences of toxigenic *A. flavus*, for many of the treated areas [BPPD review - May 15, 2003]. Reducing the aflatoxin-producing populations of fungi, and the concomitant reduction of aflatoxin, a potent carcinogen, is in the public interest. ✓ *single

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. *What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0138 in the subject line on the first page of your submission. All objections and hearing requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before *[insert date 60 days after date of publication in the Federal Register]*.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0138, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order

12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption from the tolerance requirement in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

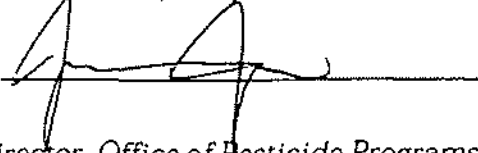
X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,
Agricultural commodities, Pesticides and pests, Reporting and
recordkeeping requirements.

Dated: 6/23/03

A handwritten signature in black ink, appearing to be 'A. A.', written over a horizontal line.

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1206 is revised to read as follows:

§ 180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

BILLING CODE 6560-50-S

Texas Irrigated Upland Cotton County Estimates 2001

For Information Contact: Betty Johnson

Link To: District Map

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
11	45	Briscoe	24,000	24,000	530	26,500
	65	Carson	5,000	4,700	735	7,200
	69	Castro	78,000	77,900	955	155,000
	117	Deaf Smith	27,000	23,000	772	37,000
	153	Floyd	125,500	120,600	653	164,000
	189	Haile	242,000	238,500	708	352,000
	205	Hartley	1,400	1,100	655	1,500
	369	Parmer	70,000	69,000	1,043	150,000
	381	Randall	2,000	2,000	600	2,500
	437	Swisher	72,000	69,500	780	113,000
12	888	Other Counties	2,100	1,700	649	2,300
	999	District 1-N	649,000	632,000	768	1,011,000
	3	Andrews	9,000	8,200	585	10,000
	17	Bailey	36,000	29,800	660	41,000
	79	Cochran	71,000	69,000	563	81,000
	107	Crosby	136,000	98,000	451	92,000
	115	Dawson	56,000	52,500	622	68,000
	165	Gaines	184,000	167,500	519	181,000
	173	Glasscock	23,500	23,000	668	32,000
	219	Hockley	139,000	92,000	522	100,000

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
	227	Howard	2,500	2,300	417	2,000
	279	Lamb	163,500	150,500	753	236,000
	303	Lubbock	171,500	131,000	447	122,000
	305	Lynn	80,500	35,800	389	29,000
	317	Martin	10,500	10,400	692	15,000
	329	Midland	8,000	7,000	480	7,000
	445	Terry	125,500	119,000	387	96,000
	501	Yoakum	63,500	61,000	567	72,000
	999	District 1-S	1,280,000	1,057,000	538	1,184,000
21	33	Borden	1,500	1,500	704	2,200
	75	Childress	6,100	6,100	708	9,000
	87	Collingsworth	5,600	5,300	860	9,500
	101	Cottle	1,800	1,800	667	2,500
	125	Dickens	3,100	3,100	325	2,100
	129	Donley	4,700	4,600	522	5,000
	169	Garza	12,200	10,600	543	12,000
	191	Hall	8,200	7,800	677	11,000
	197	Hardeman	3,000	2,800	600	3,500
	345	Motley	2,200	2,000	600	2,500
	483	Wheeler	1,300	1,200	800	2,000
	487	Wilbarger	1,000	900	693	1,300
	888	Other Counties	300	300	640	400
	999	District 2-N	51,000	48,000	630	63,000

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (balas)
22	151	Fisher	2,200	2,200	873	4,000
	207	Haskell	16,300	15,800	668	22,000
	275	Knox	16,000	16,000	846	28,200
	335	Mitchell	3,000	3,000	736	4,600
	353	Nolan	2,700	2,500	691	3,600
	399	Runnels	1,400	1,400	514	1,500
	415	Scurry	1,400	1,400	514	1,500
	888	Other Counties	2,000	1,700	734	2,600
	999	District 2-S	45,000	44,000	742	68,000
40	888	Other Counties	2,000	2,000	720	3,000
	999	District 4	2,000	2,000	720	3,000
51	888	Other Counties	1,000	1,000	480	1,000
	999	District 5-N	1,000	1,000	480	1,000
52	41	Brazos	5,400	5,400	800	9,000
	395	Robertson	18,600	18,600	568	22,000
	999	District 5-S	24,000	24,000	620	31,000
60	141	El Paso	9,000	8,700	1,324	24,000
	229	Hudspeth	8,000	8,000	1,200	20,000
	371	Pecos	6,500	6,500	849	11,500
	389	Reeves	5,700	5,200	591	6,400
	888	Other Counties	800	600	880	1,100
	999	District 6	30,000	29,000	1,043	63,000
70	95	Concho	1,600	1,600	600	2,000

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
	383	Reagan	7,400	7,400	584	9,000
	451	Tom Green	12,900	12,900	670	18,000
	461	Upton	5,300	5,300	607	6,700
	888	Other Counties	6,800	6,800	868	12,300
	999	District 7	34,000	34,000	678	48,000
81	25	Bee	1,400	1,400	1,029	3,000
	51	Burleson	7,900	7,900	711	11,700
	888	Other Counties	4,700	4,700	1,256	12,300
	999	District 8-N	14,000	14,000	926	27,000
82	409	San Patricio	7,000	7,000	1,234	18,000
	999	District 8-S	7,000	7,000	1,234	18,000
90	469	Victoria	1,000	1,000	720	1,500
	481	Wharton	5,000	5,000	912	9,500
	888	Other Counties	1,000	1,000	960	2,000
	999	District 9	7,000	7,000	891	13,000
96	507	Zavala	2,800	2,800	857	5,000
	888	Other Counties	2,200	2,200	873	4,000
	999	District 10-N	5,000	5,000	864	9,000
97	61	Cameron	36,800	35,000	617	45,000
	215	Hidalgo	42,500	40,000	780	65,000
	489	Willacy	7,600	5,900	732	9,000
	888	Other Counties	2,100	2,100	686	3,000
	999	District 10-S	89,000	83,000	706	122,000

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
99	999	Texas	2,238,000	1,987,000	643	2,661,000
When less than 1,000 planted acres of dryland or irrigated crop are estimated for a county or district, the acres and production for both practices are included in "other counties" or "other districts" to avoid disclosure.						

Texas Non-Irrigated Upland Cotton County Estimates 2001

For Information Contact: Betty JohnsonLink to: District Map

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
11	45	Briscoe	17,000	15,400	237	7,600
	65	Carson	2,200	2,100	434	1,900
	69	Castro	3,700	2,400	400	2,000
	117	Deaf Smith	8,000	6,700	394	5,500
	153	Floyd	51,600	47,000	255	25,000
	189	Hale	24,700	22,500	416	19,500
	205	Hartley	5,600	2,200	415	1,900
	369	Parmer	4,400	4,100	433	3,700
	381	Randall	2,200	1,700	424	1,500
	437	Swisher	9,200	9,000	400	7,500
12	888	Other Counties	2,400	900	480	900
	999	District 1-N	131,000	114,000	324	77,000
	3	Andrews	19,100	9,000	107	2,000
	17	Bailey	50,000	40,000	240	20,000
	79	Cochran	61,600	44,500	248	23,000
	107	Crosby	88,400	74,500	161	25,000
	115	Dawson	253,000	32,000	210	14,000
	165	Gaines	108,500	24,000	180	9,000
	173	Glasscock	68,900	7,000	206	3,000

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
	219	Hockley	118,400	73,500	229	35,000
	227	Howard	126,000	23,000	125	6,000
	279	Lamb	42,400	19,500	345	14,000
	303	Lubbock	92,500	62,500	184	24,000
	305	Lynn	219,000	74,500	209	32,500
	317	Martin	146,500	15,000	112	3,500
	329	Midland	26,800	7,000	137	2,000
	445	Terry	140,200	69,500	162	23,500
	501	Yoakum	83,700	26,500	172	9,500
	999	District 1-S	1,645,000	602,000	196	246,000
21	33	Borden	19,700	4,000	180	1,500
	75	Childress	33,300	30,000	176	11,000
	87	Collingsworth	12,500	12,000	268	6,700
	101	Cottle	17,200	12,400	135	3,500
	125	Dickens	21,200	20,000	242	10,100
	129	Donley	8,800	7,600	360	5,700
	169	Garza	32,600	13,500	142	4,000
	191	Hall	49,700	42,800	236	21,000
	197	Hardeman	4,900	2,500	192	1,000
	263	Kem	3,000	2,900	248	1,500
	345	Motley	27,700	25,000	134	7,000
	483	Wheeler	3,500	3,500	274	2,000
	485	Wichita	18,700	8,800	191	3,500

Shan-

This is great! Very well done. A few minor comments to add in. Feel free to discuss these with me if you like. I noted the pages on the meeting slip. *Janet*

June 4, 2003
Nice job Shanaz.
1) Blue edits/typos on several pages.
2) ~~Two~~ ^{Two} comments. (Consistent w/ 40 CFR)
a) Please delete acute for ecotox tests - there ~~is~~ ^{are} no such tests for microbial ^{GIS}
b) Change Environmental Fate to 'Environmental Expression'. Thanks - Gail (over)

ROUTING AND TRANSMISSION SLIP

Date

6/3/03

TO: (Name, office symbol, room number,
building, Agency/ Post)

Initials

Date

1.

Janet

2.

p. 27 p. 35, 36 minor changes

3.

"typo" 37, 38 - in brackets

4.

5.

Action

File

Note and Return

Approval

For Clearance

Per Conversation

As Requested

For Correction

Prepare Reply

Circulate

For Your Information

See Me

X Comment

Investigate

Signature

Coordination

Justify

REMARKS

AF36

Dem - asked me to give
you a copy for comments.
FR Template is here -
This is the copy I am proofing
to send up to Tim Jones.

DO NOT use this form as a RECORD of approvals, concurrences, dis-
clearances, and similar actions

FROM: (Name, org. symbol, Agency/ Post)

Shawn

Room No. — Bldg.

Phone No.

308-8097

NSN 7540-00-935-5862
5041-103



OPTIONAL FORM 41 (Rev. 1-94)

Prescribed by GSA

UNICOR FPI - SST

> AF36 BRAD

Page 1 of 1

 New Memo  Forward  Reply  Edit  Delete  Go to  Copy Info

Chris Kaczmarek To:Shanaz Bacchus/DC/USEPA/US@EPA

cc:

06/09/2003 03:50 PM

bcc:

Subject:AF36 BRAD

Shawn,

Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel
(202) 564-3909

<https://dewetmail1.epa.gov/mail/sbachus.nsf/5e502a1baaaf40ca85256197006c1a32/441f20b4aad7c9758525...> 6/9/03

Attachment #2: OPPTS Docket Verification and Certification Form



U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
(OPPTS)

1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action: *Final Rule Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance*

RIN #: 2070-

Docket ID #: *OPP-2003-0138*

FRL#:

Contact Information:

Name: *Shanaz Bacchus*

Phone: *703-308-8097*

Legacy Information:

OPP2003-0048, OPP2003-0020

Program Lead's Verification: I have reviewed the docket and verified the following:

- ☐ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- ☐ Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.
- ☐ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.
- ☒ Comments: *no support document*

Date: *4-2-03*

Initials: *Shanaz Bacchus*

Phone: *703-308-8097*

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- ☐ The Docket ID # identified above matches our records.
- ☐ The documents identified in the attached Docket Index have been received by the Docket.
- ☐ The documents have been properly processed for inclusion in EPA Dockets, as appropriate.
- ☐ The documents either already are in the docket or are being process for inclusion in the docket.
- ☒ Comments: *NO Support DOC.*

Date: *4-2-03*

Signature: *[Signature]*

Phone: *305-6434*

Program Lead's Certification: I hereby certify that:

- ☐ I have completed the verification above.
- ☐ I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.
- ☐ I have obtained the DM's sign-off.
- ☐ The docket is complete and ready for public release.
- ☐ Comments:

Date:

Signature:

Phone:



Chris Kaczmarek

06/12/03 06:31 PM

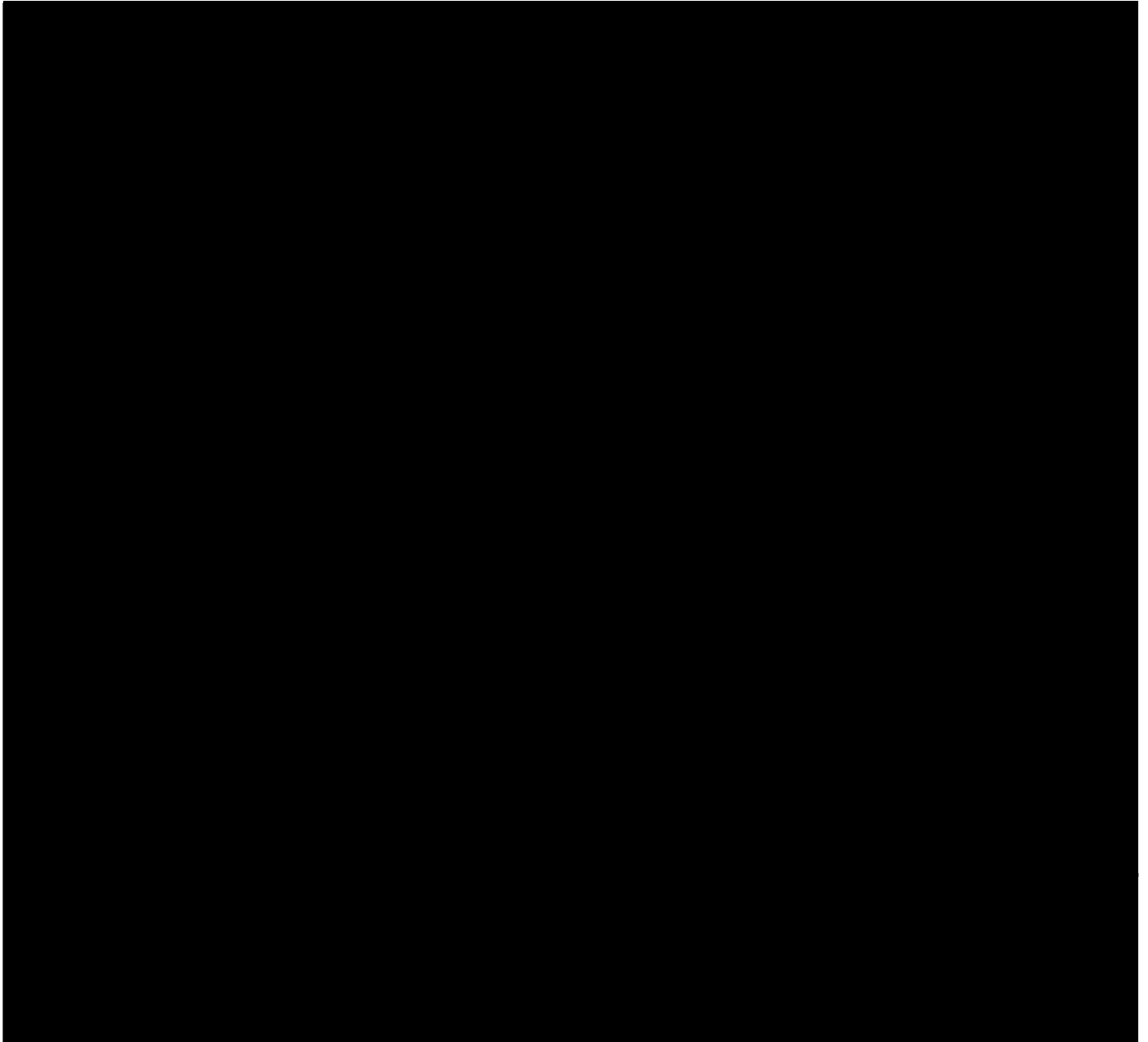
To: Shanaz Bacchus/DC/USEPA/US@EPA

CC:

Subject: AF36 BRAD

*Deliberative
Attorney-Client Communication
Attorney Work Product*

Shawn,



Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel
(202) 564-3909



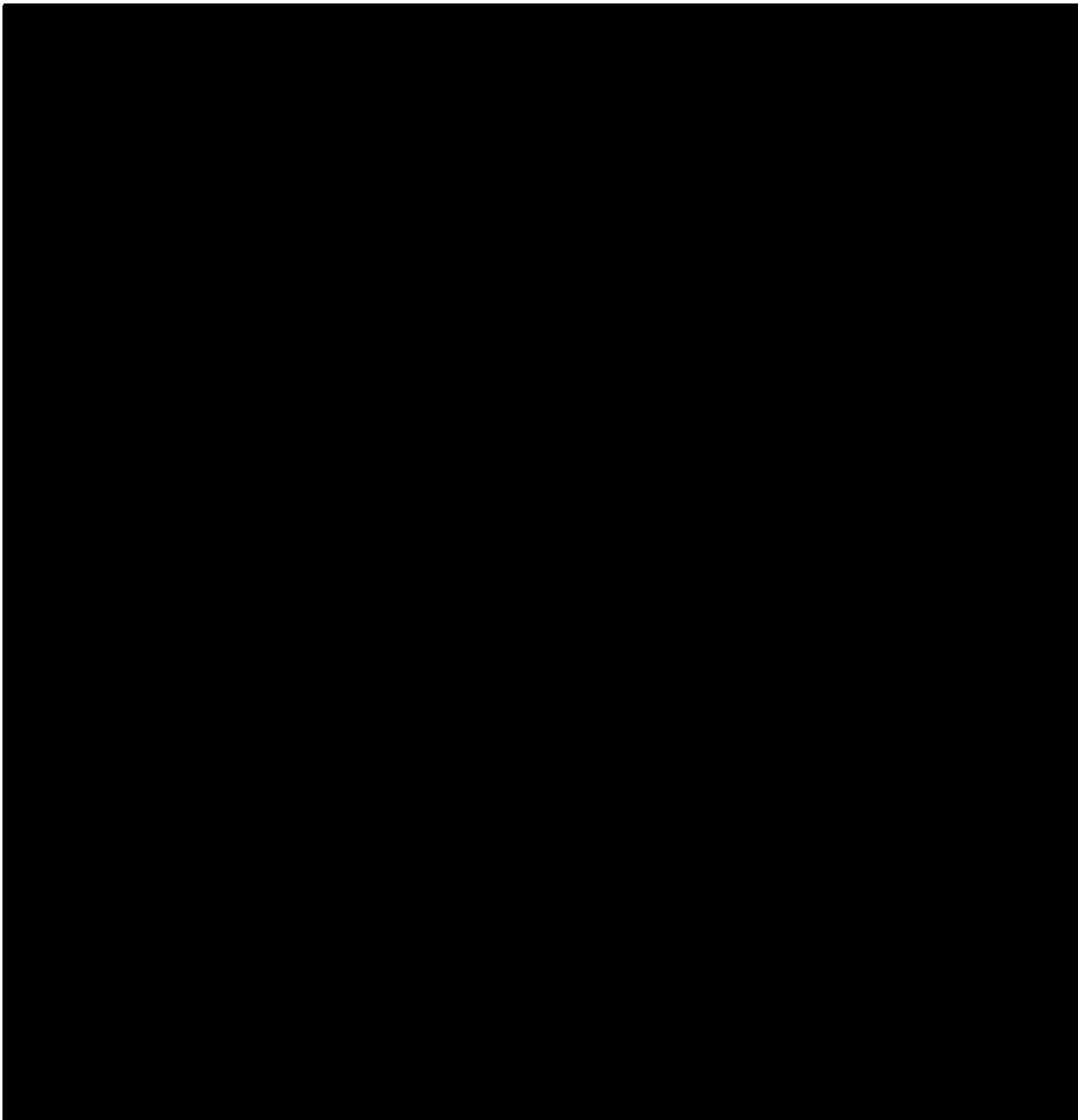
Brian Steinwand

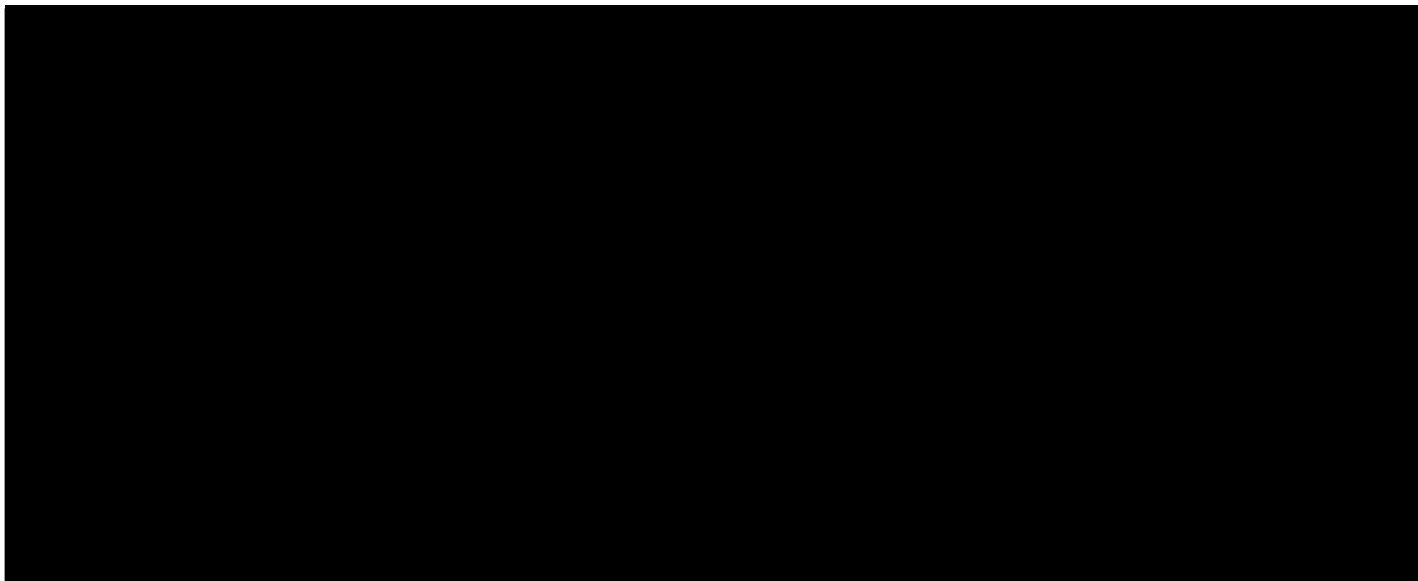
06/24/03 01:56 PM

To: OPP BPPD

CC:

Subject: ***[INTERNAL ALERT***EPA Registers Microbial Fungicide AF36
for Use on Cotton







ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

FAX TRANSMITTAL FORM

DATE: 5/23/03TO: Shanaz Bacchus FROM: Larry Antillas

DEPT./AGENCY: _____

FAX NUMBER: 703-308-7026 TOTAL PAGES: 4SUBJECT: AF36 Conditional Registration Letter

☒ URGENT ☐ EYE ☐ REPLY ☐ COMMENT ☐ RECYCLE

MESSAGE: Thank you for your help!LA

FOR MORE INFORMATION CALL: _____ PHONE: _____

**ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL**

3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

Dennis Szuhay, Acting Chief
Microbial and Plant Incorporated Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 910, Crystal Mall 2
Arlington Virginia, 22202
(703) 308-8260

May 23, 2003

RE: Pending Section 3 Registration-*Aspergillus flavus* AF36
EPA Reg. No. 71693-R; Active Ingredient # 006546
Pending Pesticide Petition # 8E5001
RAL Shanaz Bacchus (703)308-8097

Dear Dennis:

This is in response to your letter dated May 22, 2003 (attached) notifying us about our active ingredient *Aspergillus flavus* AF36 eligibility for a conditional Section 3(c)7(C) registration on cotton in AZ and TX. We are hereby committing to provide the following data within the time frames you requested as shown below as conditions of registration:

1. Guidelines 151-10 through 151-16 (OPPTS Gdln 885.1300): Product Identity

Analyses of 5 batches is required at production and must include data relevant to certification of limits, detection, identification, enumeration and rejection limits of metabolites and potential human pathogens (bacterial and fungal) using routine quality control and assurance methods to be implemented for large scale production. Batch analysis must also include viability and storage stability data. All batches containing human pathogens above regulatory levels must be destroyed. A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36. Data to remove this condition of registration must be submitted within 2.5 years of the conditional registration. If at any time the formulation, manufacturing process or quality control methods change, you must submit appropriate relevant data to amend the conditional registration of this microbial active ingredient.

Our understanding of "enumeration and rejection limits of metabolites" is that we will continue to analyze for aflatoxin in the working culture by TLC in all batches as already described in MRID 44626101 which is prior to inoculating the wheat. We agree to do the analysis for aflatoxin as a post production analysis only as part of the five batch analysis, but there will not be any post production analysis for aflatoxin as part of the routine quality control procedure.

Similarly, our understanding of "A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36" means that we will continue to utilize vegetative compatibility grouping as a test prior to and after production. We agree to use a DNA based confirmatory method only on the 5 batch analysis, but not as part of the routine quality control procedure.

2. Efficacy data are required from a large scale field trial in TX to confirm the bridging of data from Arizona to Texas and to demonstrate that *Aspergillus flavus* AF36 reduces aflatoxin-producing strains of *Aspergillus flavus*

A table clarifying these data requirements is below. Through communication with Shanaz Bacchus, we understand that you already have the appropriate final draft label for stamping. We understand that further data may be required for different formulations and application methods and other use sites, on a case by case basis, if such amendments ensue during this conditional registration.

Data required as a condition of Registration of <i>Aspergillus flavus</i> AF36			
Guideline	Title of Study	Data Required	Due Date
885.1300 151B-12	Discussion of Formation of Unintentional Ingredients	Formation of unintentional ingredients, human pathogen and metabolite identification and quantification (including aflatoxin quantification).	During production of 5 batches or 2.5 years after conditional registration date.
*885.1400 151B-13	Analysis of Samples	5 batch analysis to include viability and storage stability data.	During production of 5 batches or 2.5 years after conditional registration date.
*885.1500 151B-15	Certification of limits	Standard data requirement for production batches.	During production of 5 batches or 2 years after conditional registration date.
Non-guideline: required for public health hazard	Efficacy/Product Performance	Efficacy/Product Performance data to demonstrate the reduction of toxigenic strains by <i>A. flavus</i> AF36 in Texas.	2.5 years after conditional registration date.

Sincerely,



Larry Antilla,
Staff Director
Arizona Cotton Research and Protection Council

CC: Shanaz Bacchus, BPPD, USEPA
Phil Hutton, BPPD, USEPA
Janet Andersen, BPPD, USEPA
Peter Cotty, USDA-ARS
Phil Wakelyn, National Cotton Council

apply..etc., as per page I gave you for WPS. If you have misplaced it, drop me an email/voicemail, include a fax # and I'll fax it to you...I'm working at home on Monday 5/5, but can access both from home.

4. Ag Use requirements contain statements for early entry workers and REI. Include statements about PPE for mixer/loaders in the Directions for Use.

2nd column

5. Remove 300o cfu from position near to AF36 active ingredient listing. Put asterisk above AF36 and viability data below Total line to read " *3000 cfu/g End-use Product"

6. Include First Aid Sttatemnts in BOx for visibility as per PRN 2001-1 I sent you yesterday p.m. First Aid statements include "If on skin or clothing..."

Below First Aid statements:

"Have the product container or label with you..."

Remove redundancies to tighten up label.

I noticed when I converted it from Word to WordPerfect, it became 2 logical pages. The draft label, which we stamp does not have to be the final printed (FP) label. Of course, you don't want to have to do 2 labels, (1 draft and 1 FP) but if it's easier for you to leave the printers the job of rearranging the columns, then the 2 page WP label will be fine, assuming that the content remains the same on the FP.

Now that I've kept my promise about the label, have a great weekend, shawn

(sent sat 5/3 from home)



AF363page label.doc

Joel Gagliardi

05/06/03 12:58 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA

cc:

Subject: Re: Aflaguard/pnuts

Shawn,

Yes - i am busy most of this week. Anytime tomorrow is fine.

Joel

Shanaz Bacchus/DC/USEPA/US@EPA



Shanaz
Bacchus/DC/USEPA/U
S@EPA

05/06/2003 12:47 PM

To: Joel Gagliardi/DC/USEPA/US@EPA

cc:

Subject: Aflaguard/pnuts

Joel, let's meet tomorrow, we both have a lot to keep us busy until then, don't we?

Have a great day

shawn



Chris Kaczmarek

06/12/03 06:31 PM

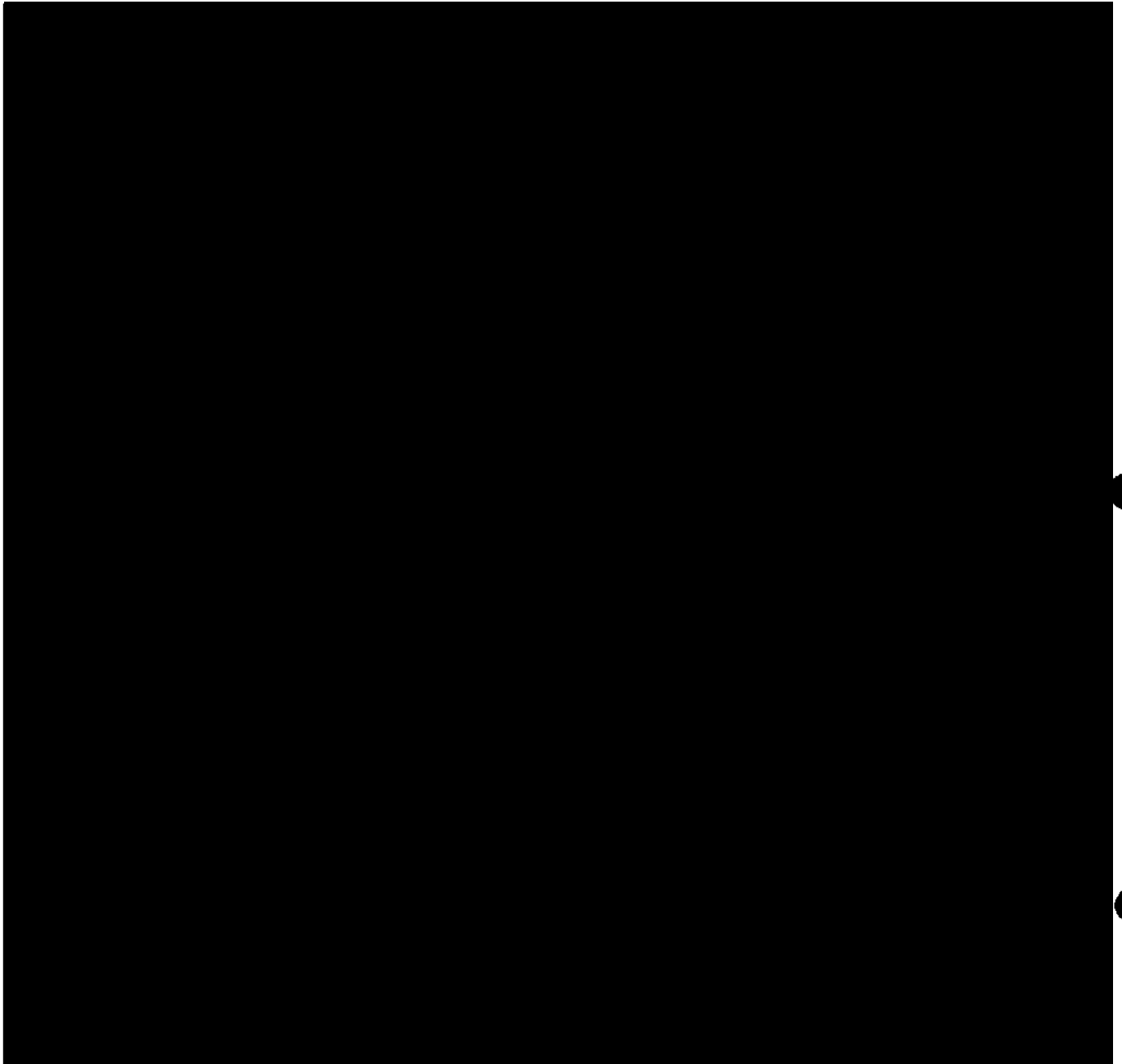
To: Shanaz Bacchus/DC/USEPA/US@EPA

CC:

Subject: AF36 BRAD

*Deliberative
Attorney-Client Communication
Attorney Work Product*


Shawn,



Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel
(202) 564-3909



Chris Kaczmarek
06/12/03 05:20 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: Re: AF36 BRAD/why not compiled 

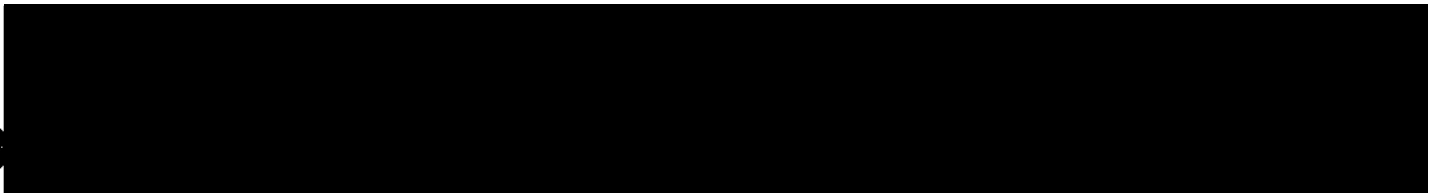


Shanaz Bacchus



Shanaz Bacchus
06/12/03 05:18 PM

To: Chris Kaczmarek/DC/USEPA/US
cc:
Subject: AF36 BRAD/why not compiled




shawn

Privileged attorney-client communication



Chris Kaczmarek

06/12/03 03:22 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: Re: AF36/receipt? 



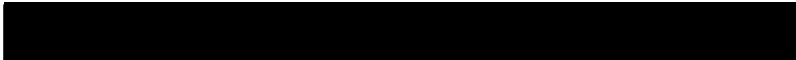
Shanaz Bacchus



Shanaz Bacchus

06/12/03 03:21 PM

To: Chris Kaczmarek/DC/USEPA/US
cc:
Subject: AF36/receipt?



Return Receipt

Your document:
was received by:
at:

AF36/receipt?

Chris Kaczmarek/DC/USEPA/US

06/12/2003 03:25:01 PM



Chris Kaczmarek
06/10/03 03:30.PM

To: John Kough/DC/USEPA/US@EPA, Shanaz
Bacchus/DC/USEPA/US@EPA
cc: Carl Etsitty/DC/USEPA/US@EPA, Dennis
Szuhey/DC/USEPA/US@EPA, Phil Hutton/DC/USEPA/US@EPA
Subject: Re: mortality and vegetative compatibility in AF36 [5]

John,

[Redacted]

Shanaz,

[Redacted]

Thanks!

Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel
(202) 564-3909

John Kough

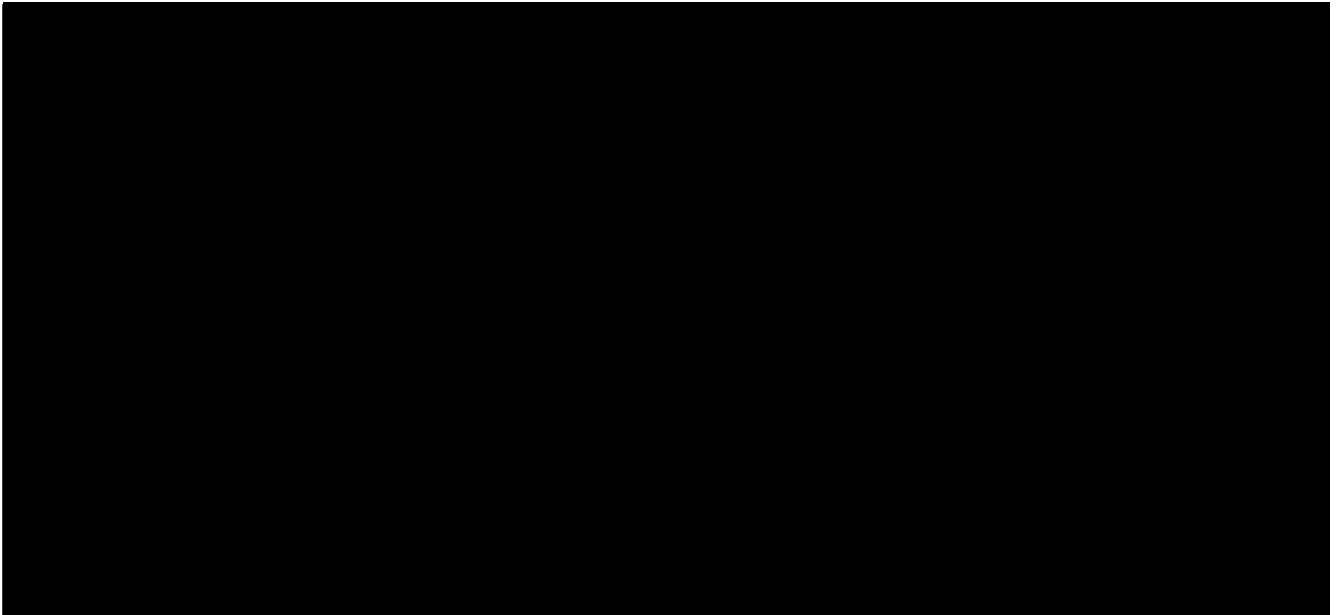


John Kough
06/10/03 03:12 PM

To: Chris Kaczmarek/DC/USEPA/US@EPA, Shanaz
Bacchus/DC/USEPA/US@EPA, Carl Etsitty/DC/USEPA/US@EPA
cc: Phil Hutton/DC/USEPA/US@EPA, Dennis
Szuhey/DC/USEPA/US@EPA
Subject: mortality and vegetative compatibility in AF36

Chris,


[Redacted]



John K.

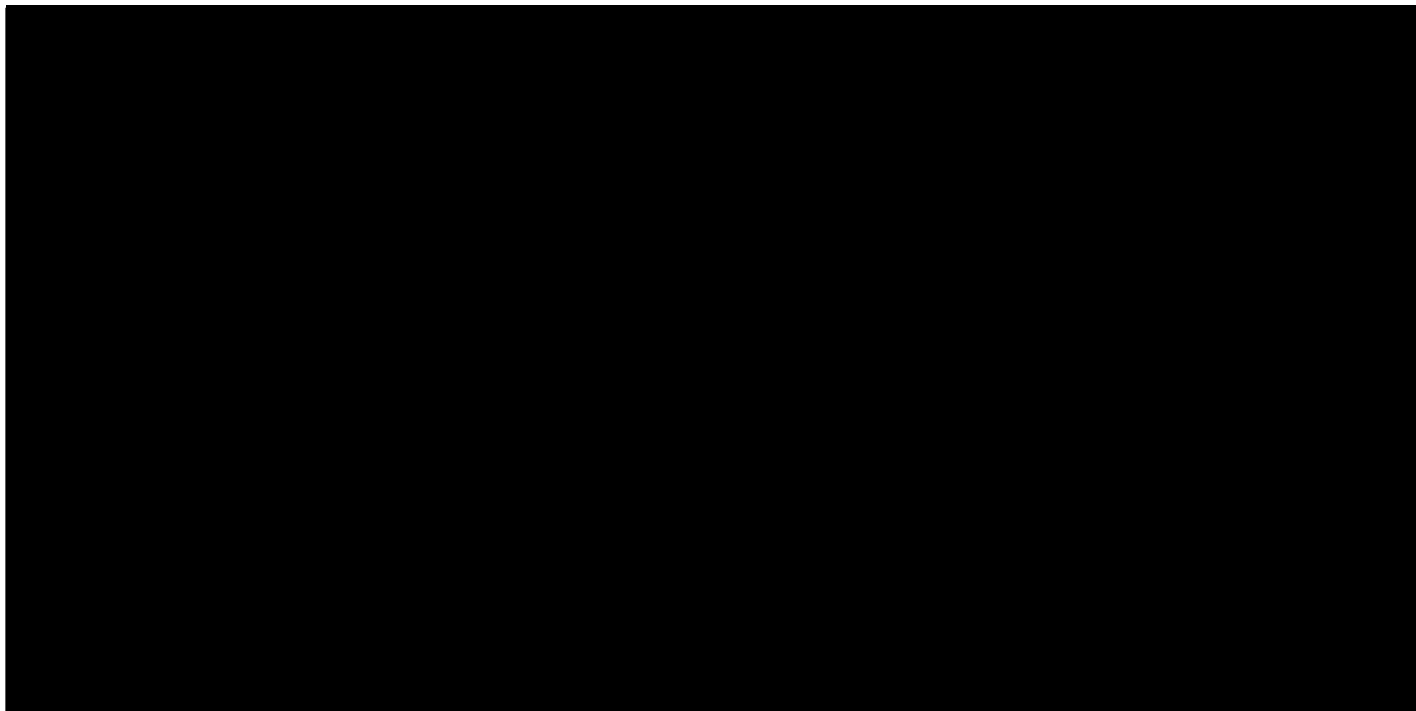


Chris Kaczmarek
06/10/03 11:44 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: Re: AF36 BRAD 

*Deliberative
Attorney-Client Communication*


Shanaz,

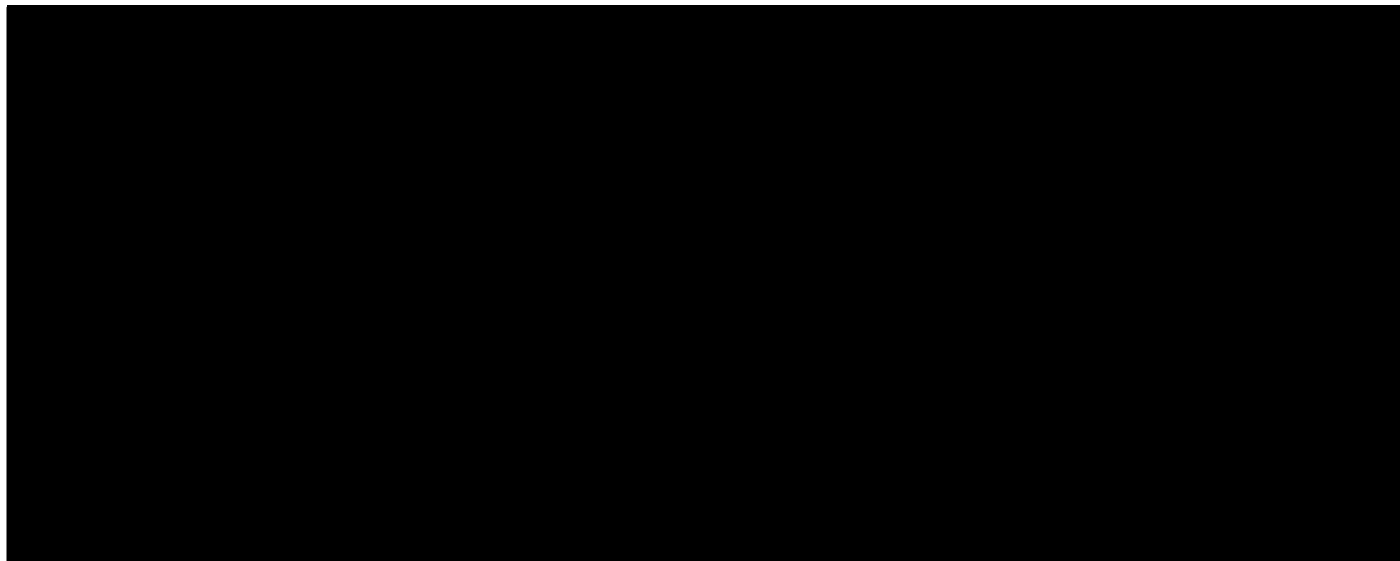


Shanaz Bacchus




Shanaz Bacchus
06/09/03 05:27 PM

To: Chris Kaczmarek/DC/USEPA/US
cc:
Subject: Re: AF36 BRAD 



Privileged attorney-client communication



Sincerely,
shawn

Privileged attorney-client communication

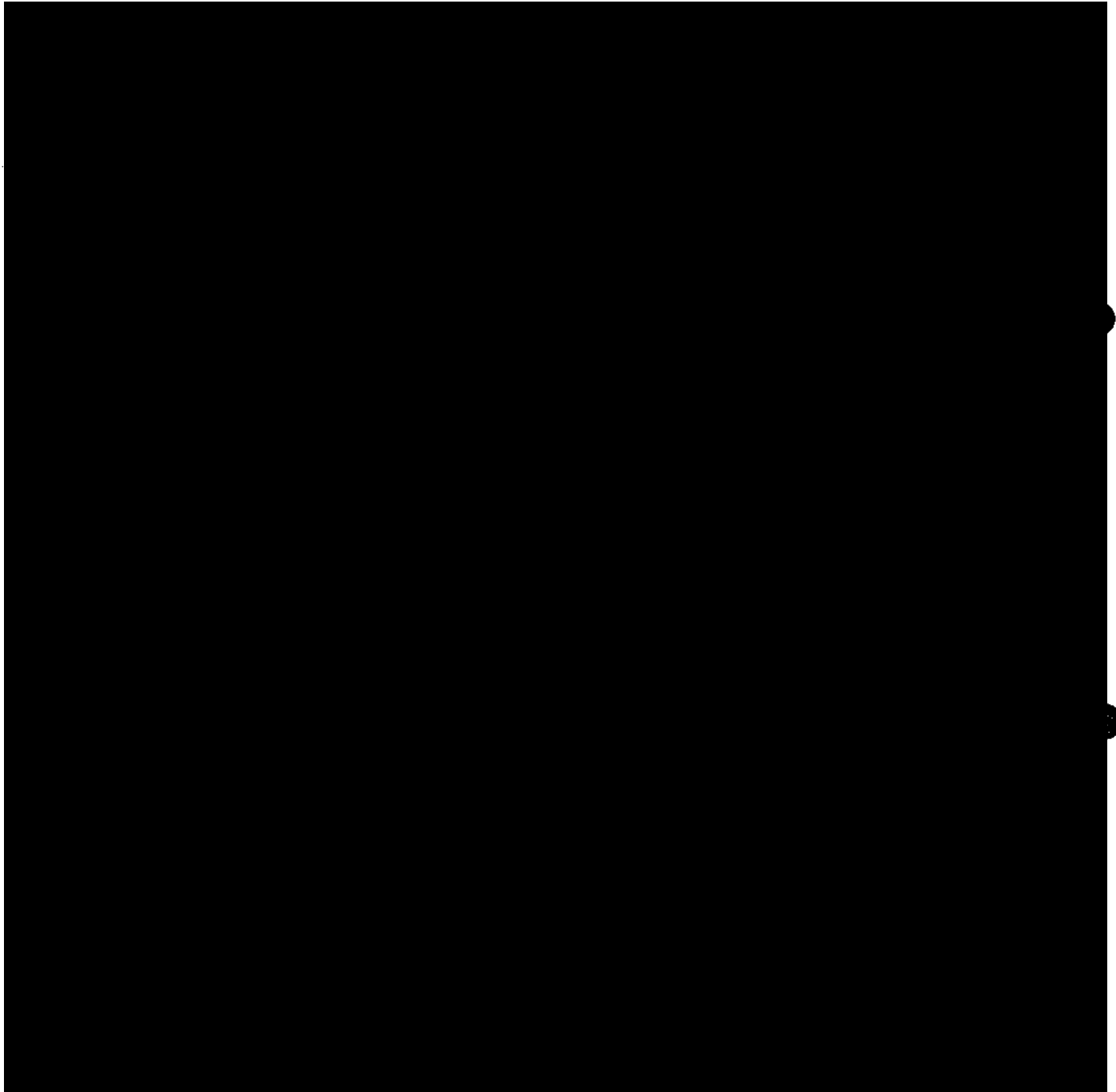


Chris Kaczmarek

06/09/03 03:50 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
CC:
Subject: AF36 BRAD

Shawn,



Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel

(202) 564-3909

Return Receipt

Your document:
was received by:
at: Revised AF36 BRAD
Chris Kaczmarek/DC/USEPA/US
06/09/2003 08:41:07 AM

Privileged attorney-client communication




Chris Kaczmarek

06/06/03 03:41 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA

cc:

Subject: Re: 3c7C para/AF36 BRAD 



Shanaz Bacchus




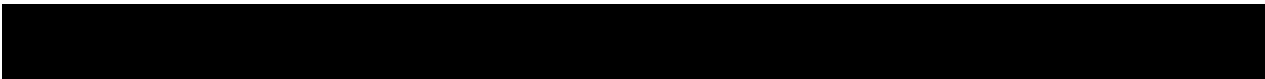
Shanaz Bacchus

06/06/03 12:17 PM

To: Chris Kaczmarek/DC/USEPA/US

cc:

Subject: Re: 3c7C para/AF36 BRAD 




shawn



Chris Kaczmarek

06/06/03 10:52 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: Re: 3c7C para/AF36 BRAD 

Shawn,

[REDACTED]

[REDACTED]

Privileged attorney-client communication




Chris Kaczmarek

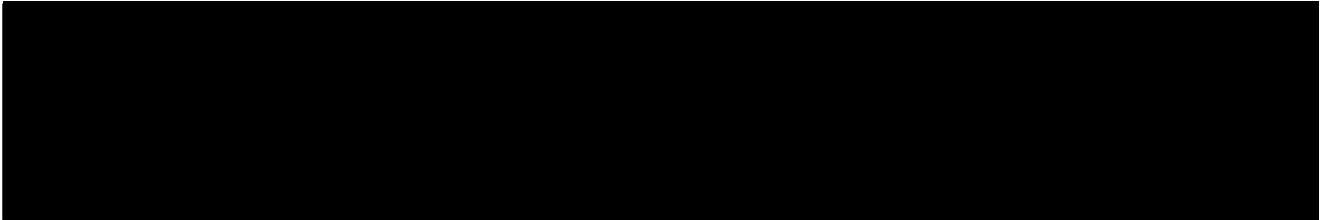
06/06/03 10:48 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA

cc:

Subject: Re: 3c7C para/AF36 BRAD 

Shawn,



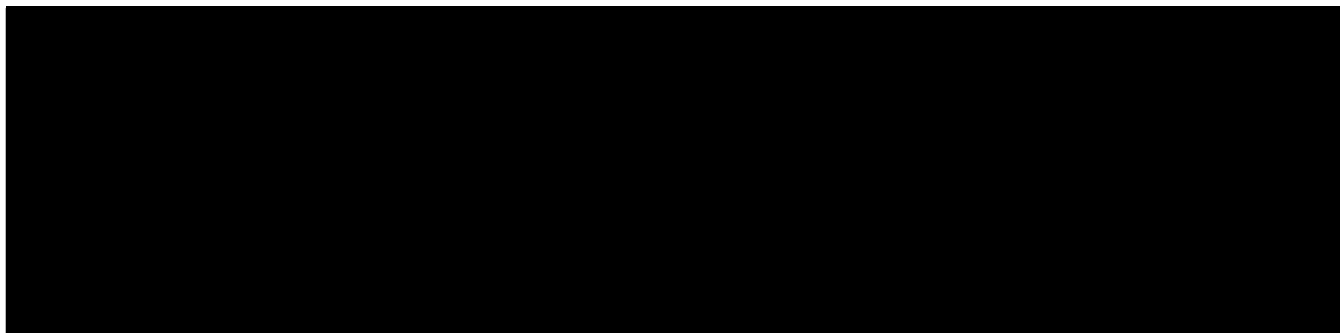


Chris Kaczmarek
06/04/03 05:56 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: AF36 BRAD

Deliberative
Attorney-Client Communication
Attorney Work Product

Shawn,



Chris E. Kaczmarek
Pesticides and Toxic Substances Law Office
Office of General Counsel
(202) 564-3909



Chris Kaczmarek

05/30/03 11:03 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA

cc:

Subject: Re: AF36/Draft BRAD/any comments?



Shanaz Bacchus



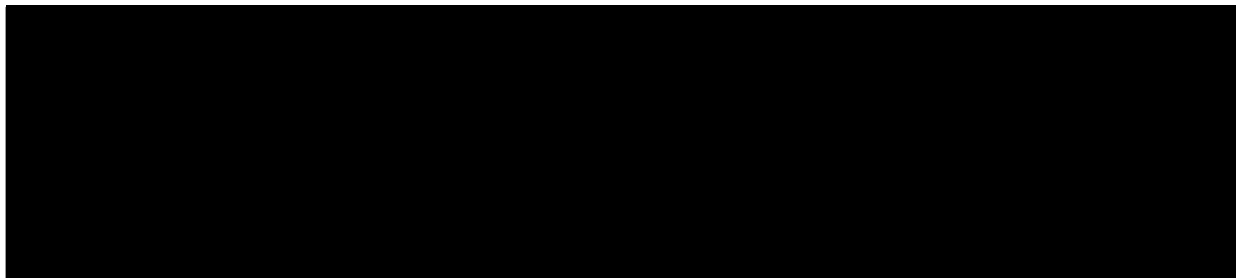
Shanaz Bacchus

05/30/03 11:05 AM

To: Chris Kaczmarek/DC/USEPA/US@EPA

cc:

Subject: Re: AF36/Draft BRAD/any comments?



Thanks.

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511C)

Biopesticides and Pollution Prevention Division

1200 Pennsylvania Ave., N.W.

Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

..... Forwarded by Shanaz Bacchus/DC/USEPA/US on 05/30/03 11:00 AM



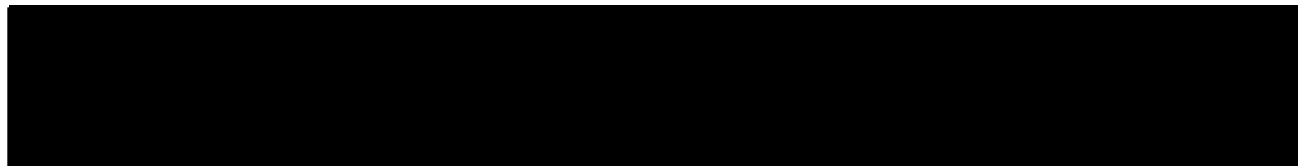
Shanaz Bacchus

05/21/03 01:47 PM

To: Chris Kaczmarek/DC/USEPA/US

cc:

Subject: Re: AF36/Draft BRAD




shawn



Chris Kaczmarek

05/20/03 05:14 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: Re: AF36 




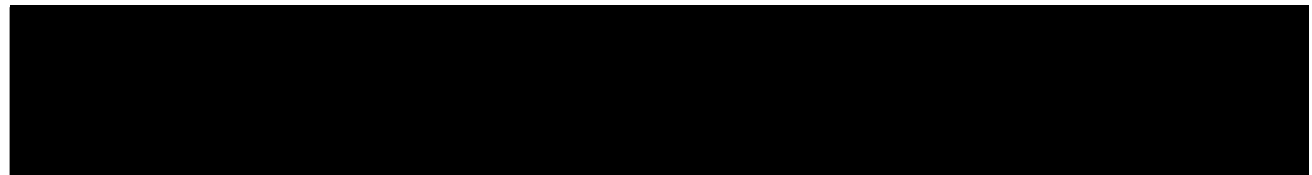
Shanaz Bacchus



Shanaz Bacchus

05/20/03 01:40 PM

To: Chris Kaczmarek/DC/USEPA/US
cc:
Subject: Re: AF36 

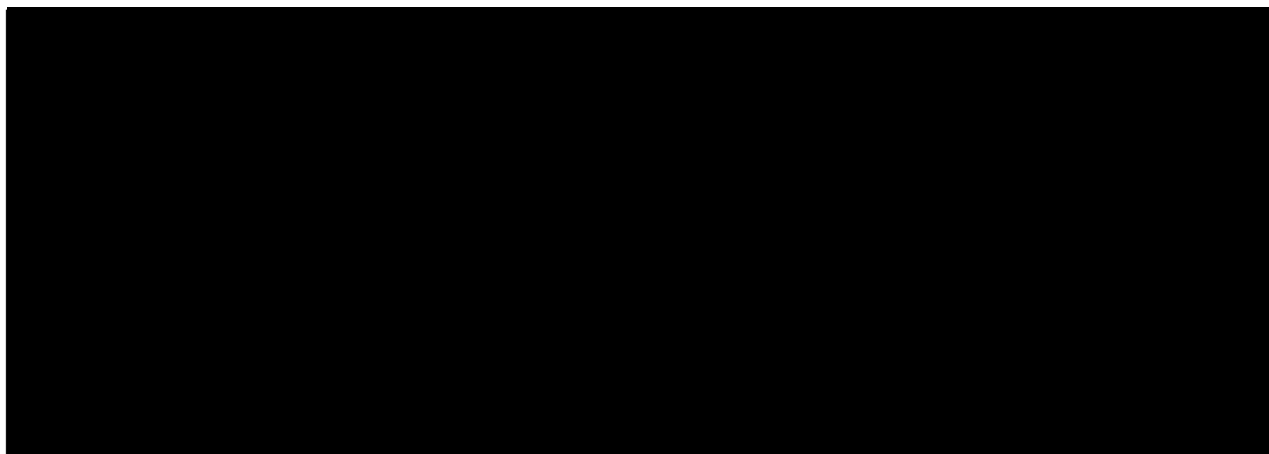


shawn



Chris Kaczmarek
05/20/03 11:31 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
CC:
Subject: Re: AF36 [icon]



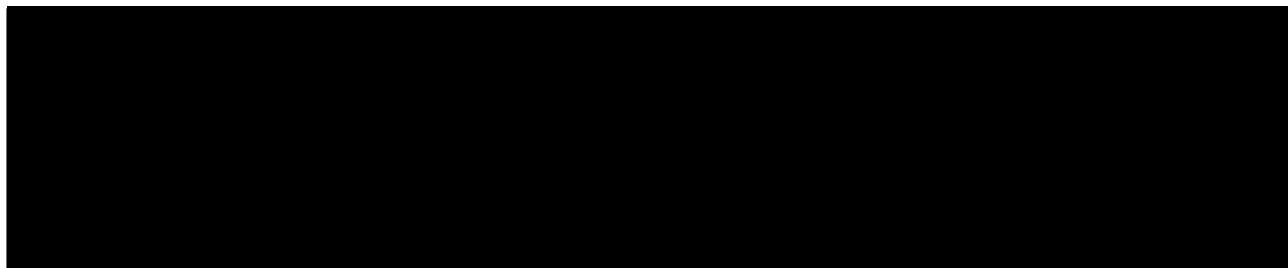
Chris!

Shanaz Bacchus



Shanaz Bacchus
05/20/03 11:12 AM

To: Chris Kaczmarek/DC/USEPA/US
cc: Shanaz Bacchus/DC/USEPA/US@EPA, Amber Aranda
Subject: Re: AF36 [icon]



shawn



Chris Kaczmarek

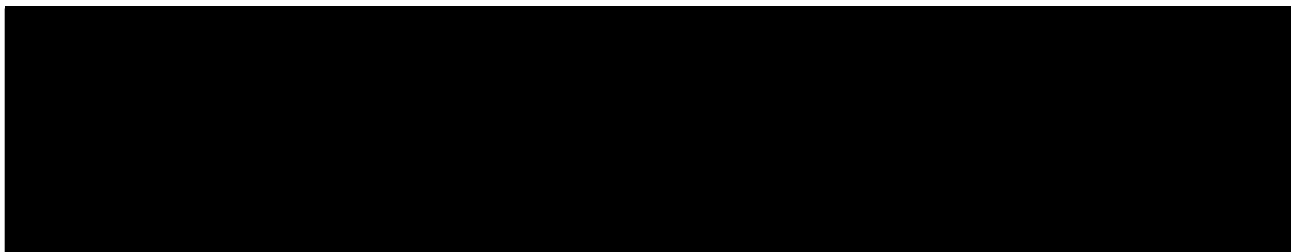
05/13/03 03:11 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA

cc: Amber Aranda

Subject: AF36

Shan,

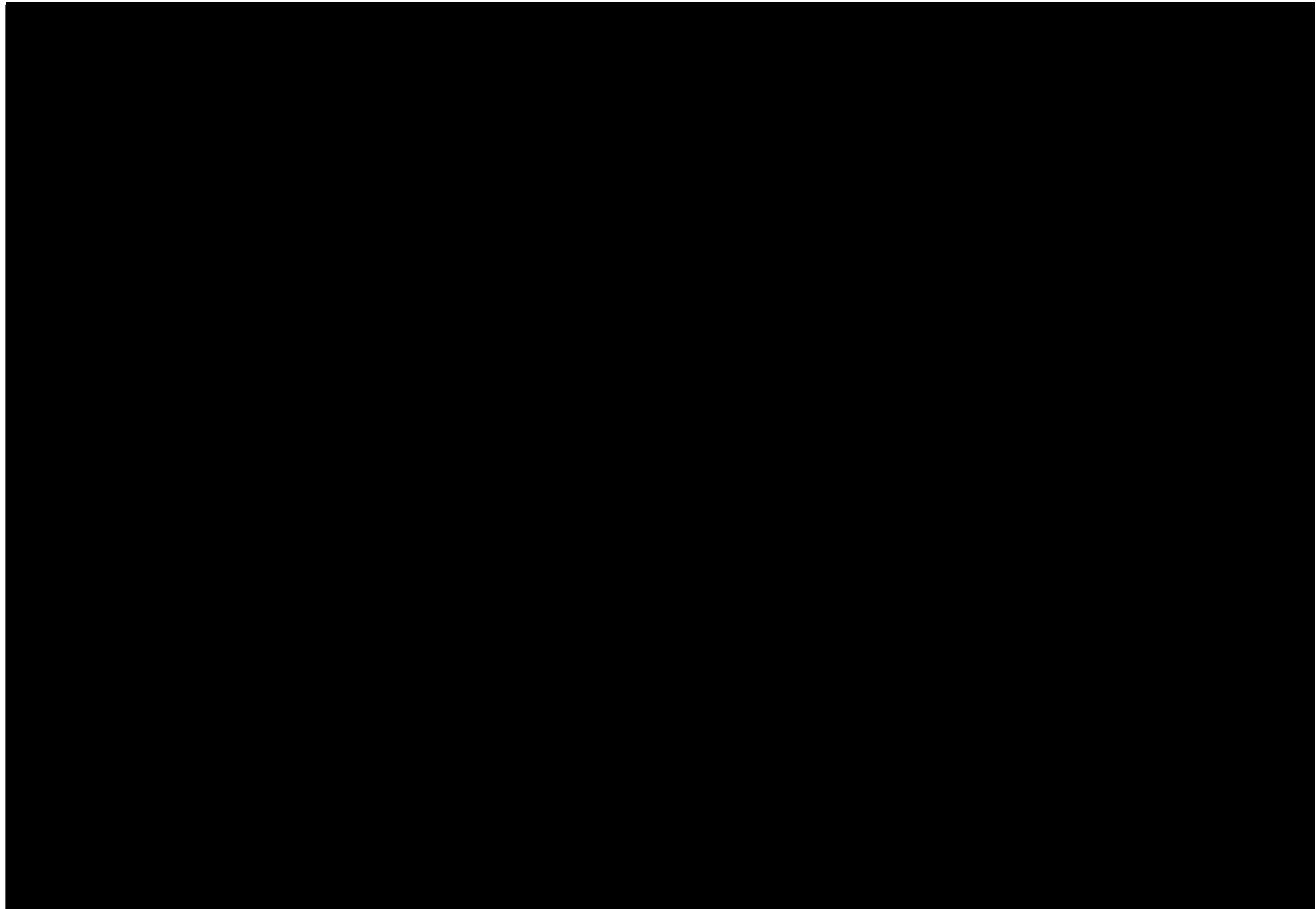




Chris Kaczmarek
05/09/03 05:52 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Dennis Szuhay/DC/USEPA/US@EPA, Kevin
Lee/DC/USEPA/US@EPA, Amber Aranda
Subject: Comments on AF36

Shanaz,



Thanks, Chris
(202) 564-3909

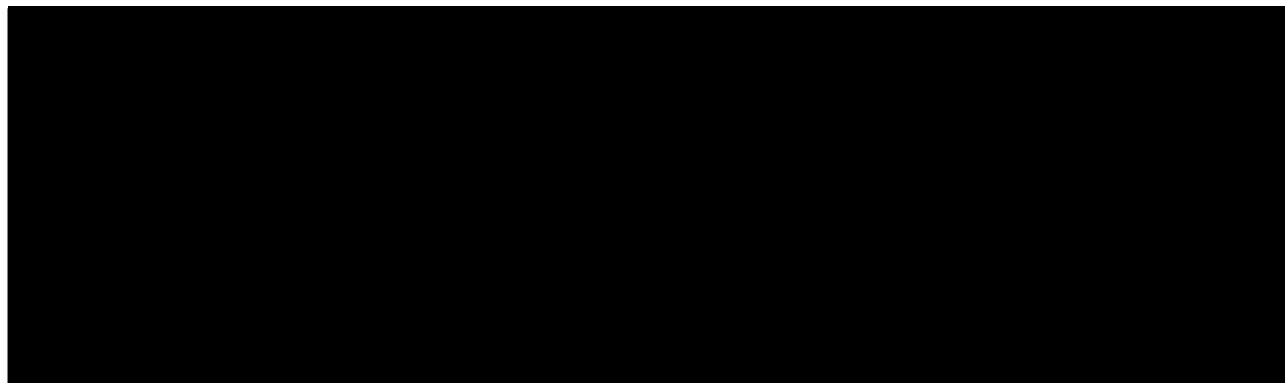
Personal privacy information



Chris Kaczmarek
05/01/03 04:41 PM

To: Shanaz Bacchus [REDACTED], Shanaz
Bacchus/DC/USEPA/US@EPA
cc: Amber Aranda
Subject: Re: AF36 template/citations [REDACTED]

Shan,



Chris

Shanaz Bacchus [REDACTED]

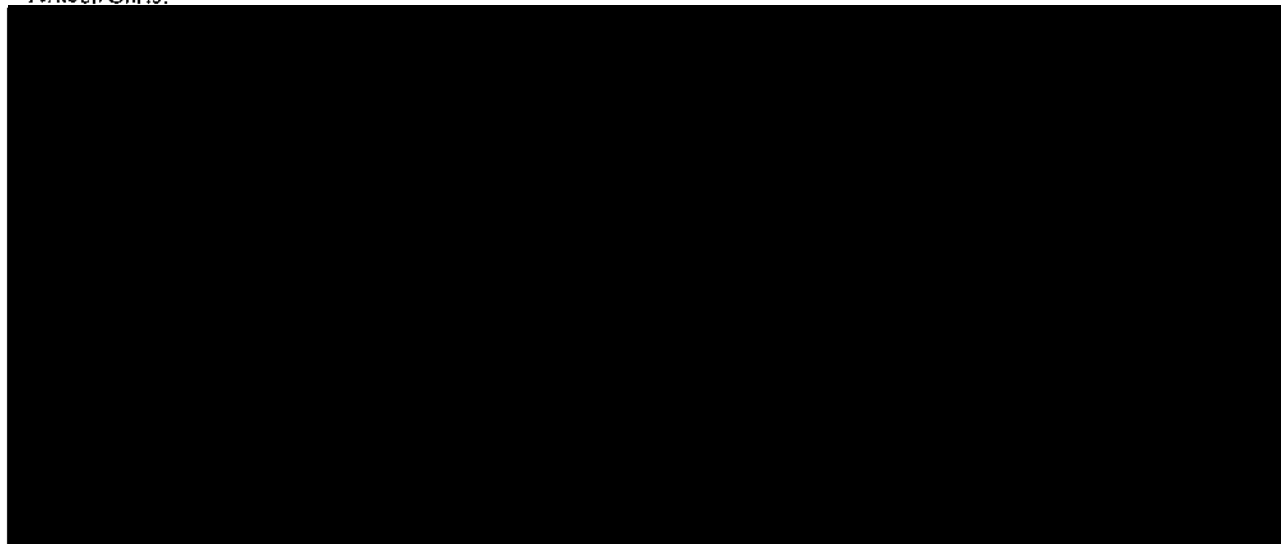


Shanaz Bacchus

05/01/03 01:46 PM

To: Amber Aranda/DC/USEPA/US@EPA, Chris
Kaczmarek/DC/USEPA/US@EPA
cc: John Kough/DC/USEPA/US@EPA, Carl
Etsitty/DC/USEPA/US@EPA, Phil Hutton/DC/USEPA/US@EPA,
Dennis Szuhay/DC/USEPA/US@EPA
Subject: AF36 template/citations

Amber/Chris:



Thanks
Shanaz Bacchus, RAL
BPPD

703-308-8097

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
	487	Wilbarger	30,000	25,000	161	8,400
	888	Other Counties	16,200	5,000	202	2,100
	999	District 2-N	299,000	215,000	199	89,000
22	83	Coleman	5,000	3,500	192	1,400
	151	Fisher	71,500	64,500	223	30,000
	207	Haskell	79,400	76,000	202	32,000
	275	Knox	13,500	10,500	229	5,000
	335	Mitchell	55,600	40,000	180	15,000
	353	Nolan	53,000	48,000	175	17,500
	399	Runnels	55,900	50,000	206	21,500
	415	Scurry	63,000	51,000	179	19,000
	888	Other Counties	128,100	102,500	214	45,600
	999	District 2-S	525,000	446,000	201	187,000
30	49	Brown	2,200	500	192	200
	77	Clay	1,700	1,000	144	300
	417	Shackelford	2,500	2,400	260	1,300
	447	Throckmorton	3,400	2,500	154	800
	888	Other Counties	2,200	1,600	120	400
	999	District 3	12,000	8,000	180	3,000
40	27	Beil	1,500	1,500	416	1,300
	85	Collin	2,900	2,800	360	2,100
	119	Delta	1,300	1,200	440	1,100
	139	Ellis	35,000	34,200	441	31,400

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
	217	Hill	23,200	23,000	361	17,300
	231	Hunt	3,500	3,400	452	3,200
	277	Lamar	2,900	2,900	364	2,200
	293	Limestone	3,000	3,000	400	2,500
	349	Navarro	17,300	17,000	339	12,000
	491	Williamson	21,800	20,800	508	22,000
	888	Other Counties	20,600	19,200	498	19,900
	999	District 4	133,000	129,000	428	115,000
51	888	Other Counties	7,000	6,000	480	6,000
	999	District 5-N	7,000	6,000	480	6,000
52	41	Brazos	2,400	2,100	480	2,100
	395	Robertson	3,100	2,900	314	1,900
	471	Walker	1,300	1,100	524	1,200
	888	Other Counties	1,200	900	427	800
	999	District 5-S	8,000	7,000	411	6,000
70	95	Concho	27,300	24,500	186	9,500
	307	McCulloch	3,900	3,500	165	1,200
	383	Reagan	30,800	1,200	320	800
	413	Schleicher	7,500	6,000	392	4,900
	451	Tom Green	74,800	66,800	259	36,000
	461	Upton	12,000	400	240	200
	888	Other Counties	4,700	600	320	400
	999	District 7	161,000	103,000	247	53,000

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
81	15	Austin	4,300	2,600	628	3,400
	25	Bee	11,700	11,700	431	10,500
	51	Burleson	3,200	3,100	387	2,500
	55	Caldwell	3,300	3,100	449	2,900
	89	Colorado	6,800	4,100	644	5,500
	175	Goliad	1,500	1,500	480	1,500
	255	Karnes	1,200	1,200	480	1,200
	453	Travis	3,300	3,100	294	1,900
	888	Other Counties	2,700	2,600	480	2,600
	999	District 8-N	38,000	33,000	465	32,000
82	273	Kleberg	43,300	18,000	427	16,000
	355	Nueces	144,600	117,000	570	139,000
	391	Refugio	41,200	40,600	875	74,000
	409	San Patricio	125,000	123,500	591	152,000
	888	Other Counties	900	900	533	1,000
	999	District 8-S	355,000	300,000	611	382,000
90	39	Brazoria	7,700	7,700	692	11,100
	57	Calhoun	27,500	25,800	683	36,700
	239	Jackson	35,500	30,500	738	46,900
	469	Victoria	18,300	15,700	605	19,800
	481	Wharton	74,000	70,500	783	115,000
	888	Other Counties	95,000	90,800	732	138,500
	999	District 9	258,000	241,000	733	368,000

District Code	County FIPS Code	District and County	Acreage Planted (acres)	Acreage Harvested (acres)	Yield per Harvested Acre (pounds)	Production (bales)
96	131	Duval	1,500	900	480	900
	888	Other Counties	20,500	17,100	396	14,100
	999	District 10-N	22,000	18,000	400	15,000
97	61	Cameron	44,600	13,000	247	6,700
	215	Hidalgo	42,500	8,500	282	5,000
	489	Willacy	80,000	19,000	202	8,000
	888	Other Counties	900	500	288	300
	999	District 10-S	168,000	41,000	234	20,000
99	999	Texas	3,762,000	2,263,000	339	1,599,000
When less than 1,000 planted acres of dryland or irrigated crop are estimated for a county or district, the acres and production for both practices are included in "other counties" or "other districts" to avoid disclosure.						

RE: AF36/last laps

Page 1 of 1

 New Memo  Forward  Reply  Edit  Delete  Go to  Copy Info

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

To: Shanaz Bacchus/DC/USEPA/US@EPA, Shanaz Bacchus
cc: Peter Cotty <pcotty@srrc.ars.usda.gov>
bcc:

06/09/2003 08:12 AM AST

Subject: RE: AF36/last laps

Shanaz

These are the numbers I received from Peter

Following is requested data (as near as I can figure):

Year Amount Used

1996 1,120.00

1997 4,630.00

1998 4,980.00

1999 105,624.00

2000 170,009.00

2001 199,454.00

2002 187,992.00

2003 200,000.00 Projected

Grand Total to 2003 873,809.00 Total

Looking forward to the BRAD

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

<https://dewebmail1.epa.gov/mail/sbachus.nsf/5e502a1baaaf40ca85256197006c1a32/e1a531bb4ba931598525...> 6/9/03

RE: AF36/cottonseed meal/cottonseed oil

Page 1 of 2



Mike Braverman
<braverman@AESOP.RUTGERS.EDU>
06/16/2003 09:51 AM AST

To: Peter Cotty <pjcott@srcc.ars.usda.gov>, Shanaz Bacchus/DC/USEPA/US@EPA
cc: [REDACTED]
bcc:
Subject: RE: AF36/cottonseed meal/cottonseed oil

Shanaz

In relation to questions A and B below...

A. See MRID 43763403 page 624 which is from a journal article: Influence of Field Application of an atoxigenic strain of *A. flavus* on the populations of *A. flavus* infecting cotton bolls and on the aflatoxin content of cottonseed.

There is no change in the total population of *A. flavus* compare to the control due to treatment with AF36 only the composition. In addition direct feeding in mamalian acute oral studies showed no adverse affect.

thermore, the fungus is killed during oil extraction with organic solvent such as hexane, the leftover part is the cottonseed meal

B. This is what constitutes efficacy. There is no increase in aflatoxin due to treatment with AF36, there is a decrease. See the same article cited above. Aflatoxin is not oil soluble and thats why it stays with the meal.

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
Website www.cook.rutgers.edu/~ir4

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Sunday, June 15, 2003 12:16 PM
To: Mike Braverman
Subject: RE: AF36/cottonseed meal/cottonseed oil

Please bear with me, because I have not looked at the data submissions and I'm looking for hard data which may be already available.

Does Peter have any data to show that:

a. AF36, the fungus (hyphae, mycelia, conidia, etc.,) is not found in cottonseed meal and cottonseed oil? Or if there are data to show that *Aspergillus* is normally found in these food commodities, do they show that the levels of *Aspergillus* found in the controls are not any greater than those treated?

b. aflatoxin levels in these food commodities (cottonseed meal and cottonseed oil) do not change above background aflatoxin levels as a

<https://dcwebmail1.epa.gov/mail/sbachus.nsf/5e502a1baaaf40ca85256197006c1a32/a235d7f1700b84b9852...> 6/16/03

Personal privacy information



Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: [REDACTED]
Subject: RE: AF36

06/13/03 10:52 AM

Shanaz

I pasted Peters previous message below which were the pounds of formulated material. The label states that the formulation contains 0.0008% a.i. so I took the numbers below and mutiplied them by 0.000008 to get the pounds of a.i.

Year	Pounds AI
1996	0.00896
1997	0.03704
1998	0.0398
1999	0.8449
2000	1.3601
2001	1.5956
2002	1.5039
2003	1.6
TOTAL	6.99

PETERS PREVIOUS NUMBERS:.....

Following is requested data (as near as I can figure):

Year Amount Used

1996 1,120.00
1997 4,630.00
1998 4,980.00
1999 105,624.00
2000 170,009.00

2001 199,454.00

2002 187,992.00

2003 200,000.00 Projected

1996 to 2003 873,809.00 Total

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Thursday, June 12, 2003 5:10 PM

To: Mike Braverman

Subject: Re: AF36

I am sincerely hoping that by June 18 I can hand you a registered label, registration notice, etc. Did you and Peter ever check the # lbs active ingredient used for the experimental years? Is that ~ 0.01 lb ai/acre = 10 lb EP? another way of saying this is: Does the estimate of the lbs EP used during the EUP = 8738.09 lb and does Peter have to manufacture 2000 lb ai for 2003?

So there's a way you can help me now (smile) and please reply ASAP (within the next 24 hrs or less).

Thanks.

Sincerely,

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman <braverman@AESOP.RUTGERS.EDU>

06/12/2003 03:34 PM AST

To: Shanaz Bacchus/DC/USEPA/US@EPA

cc:

bcc:

Subject: AF36

Shanaz

I noticed the FR notice on the A. flavus for peanut. How is it looking for

AF36. I will be at EPA on June 18th if that helps anything.

Michael Braverman, Ph.D

Biopesticide Coordinator

IR-4 Project, Rutgers University

Technology Centre of New Jersey

681 U.S. Highway 1 South

North Brunswick, New Jersey 08902-3390

Tel (732)932-9575 ext 610

FAX (732)932-8481

braverman@aesop.rutgers.edu

IR-4 Website www.cook.rutgers.edu/~ir4

=

D. Occupational and Residential Exposure:

- reduced toxigenic strains
- 400 foot boundaries
- PPE (long sleeve shirt, long pants, shoes, socks, respirator), REI 4 hrs (coveralls)

4. Ecological Exposure and Risk

A. Avian oral

- acute avian oral infectivity/pathogenicity waived during EUP pending acute avian infectivity/pathogenicity

B. Avian inhalation

- inhalation route most likely associated with aspergillosis, which is most commonly linked to *A. fumigatus*
- no treatment-related effects or clinical signs of toxicities/pathogenesis.
- acceptable

C. Honey bees

- potential for chalkbrood in bees - but study demonstrates nonhazardous to honey bees
- Honeybees study supplemental - honey bees visit cotton flowers, but do not collect their pollen.

D. Waived:

1. Non-target insects
2. Fresh water & marine aquatic vertebrates and invertebrates (granular, low runoff and exposure)
3. Non-target terrestrial and aquatic plants (normal soil & plant colonizer)
4. Wildlife (mammalian acute oral (IV); pulmonary (III) from health effects)

E. Endangered species

- carnivorous birds not at-risk - pesticide supplied on wheat seed matrix
- omnivorous birds - insects managed in cotton fields - low exposure to AF36
- *A. flavus* spp. - natural soil and plant colonizer associated with plant debris
- granular nature of pesticide minimizes drift and runoff
- labeled for endangered species during EUP pending avian inhalation study evaluation

5. Efficacy

- required of all pesticides which have claims to control a pest which endangers public health
- seasonal population data submitted and reviewed from Soil and air monitoring studies, suggesting that: AF36 displaces aflatoxin-producing strains on cotton crop

6. Public Interest Finding

- Public health hazard
- There are no alternatives registered specifically for reduction of populations of

April 7, 2003

aflatoxin-producing, *Aspergillus flavus*.
- savings cotton industry

6. Recommendations and Conditions of registration

5 batch analysis (to include nominal limits, viability, storage stability of production batches) (submitted by March 2004)

Efficacy data TX during first large scale application - TX (submitted by 2004 March)

Team Members

Health Effects

John Kough, Ph.D. Senior Scientist
Carl Etsitty, M.Sc.
Cindy Schaffer, M.Sc. (previous reviewer)
Mike Watson, Ph.D. (previous reviewer)

Regulations

Shanaz Bacchus, M.Sc., MBA.

OGC

Suzanne Krolkowski (Attorney)
Laurel Celeste (Attorney)

Managers

Janet L. Andersen, Ph.D. (Division Director)
Phil Hutton, M.Sc. (Deputy Div. Dir, Acting)
Dennis Szuhay, M.Sc. (Chief, Microbial Pesticides Branch, Acting)
Jim Downing, LL.B (Team Leader, Microbial Pesticides Branch, Acting)

Ecological Effects

Zigfridas Vaituzis Ph. D., Senior Scientist
Gail Tomimatsu, Ph. D.
Alan Reynolds, M.Sc.
Joel Gagliardi, Ph. D.

Tony Long van Steynman (Ph.D.)
Robert F. ... Ph.D.

April 7, 2003

This is for your consideration, not to be sent to J. Jones

Questions:

- 1. Do we need any dermal studies for the ground-in furrow treatment? ...the label recommends no cultivation after application and it is also a 1 time prebloom application. Both suggest low exposure.*
- 2. Do we want production batch analysis within 1 year? Or longer monitoring?*
- 3. Do we want more than 1 or 2 year efficacy trials in Texas?*
- 4. Do we still need 400 ft. boundaries around hospitals, daycares, schools etc. Yes, in my humble opinion--err on the side of precautionary.*

Conference Call with EPA Thursday, March 13th, 2003 at 2:30 PM EST

The following ten individuals are potential participants in conference call from outside EPA:

- ✓ Dr. Phil Wakelyn, Senior Scientist, National Cotton Council, Washington, DC
- ✓ Dr. Michael Braverman, Biopesticide Manager, IR-4, Rutgers University, New Brunswick, NJ
- ✓ Larry Antilla, Staff Director, Arizona Cotton Research and Protection Council, Phoenix, AZ
- ✓ Dr. Peter J. Cotty, Research Plant Pathologist, USDA, ARS, SRRC, New Orleans, LA
- ✓ Dr. Jane F. Robens, National Program Leader, USDA, ARS, Beltsville, MD
- ✓ Jeff Nunley, Executive Vice President, South Texas Cotton and Grain Association, Victoria, TX
- ✓ Craig Shook, Chairman of the Board, South Texas Cotton and Grain Association, Victoria, TX
- ✓ Clyde Sharp, President, Arizona Cotton Growers Association, Phoenix Arizona
- ✓ Hollis Sullivan, Manager, Valley Cooperative Oil Mill, Harlingen, Texas

✓ Bobbie Krum



Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Peter Cotty <picotty@srcc.ars.usda.gov>
Subject: AF36 cotton forage

06/17/03 10:36 AM

Dear Shanaz

In regard to your question about the use of cotton forage and AF36, most cotton is defoliated so cotton forage would be an extremely minor feed item. Cotton leaves and stems would be left in the field and any cleaned out in the ginning process would also be dumped back onto the field. Any other remaining vegetation would be plowed under. Plowing under of all cotton plant debris is mandatory under the boll weevil eradication program. In addition, cotton forage would not influence dietary exposure for the following reasons:

- 1) There would be no secondary transfer of the organism AF36 into milk and milk.
- 2) Mamalian acute oral studies did not indicate any adverse effects and the clearance of AF36 occurred in both rats and birds.
- 3) AF36 is already naturally occurring in soils producing cotton, corn, and wheat so a cow eating any feed that has had any exposure with soil is already consuming AF36.
- 4) AF36 only changes the composition of the *A. flavus* population in soil and subsequently plant debris by decreasing *A. flavus* strains that produce aflatoxin. It does not significantly increase the total *Aspergillus* population
- 5) AF36 is applied as a granule so it is not sprayed onto cotton foliage.

Please let me know if there are any other questions.

Thanks

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732) 932-9575 ext 610
FAX (732) 932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

BB-828 RJ



Shanaz Bacchus

To: Group Information-Svcs-Ctr@EPA

03/26/2003 03:13 PM

CC:

Subject: MRID request

----- Forwarded by Shanaz Bacchus/DC/USEPA/US on 03/26/03 03:09 PM -----



POSTED MESSAGE FROM: Sara Roman

POSTED ON: 02/23/98 02:08:43 PM



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Name: Shanaz Bacchus

ID Number: 0173 036083

Phone: 703-308-8097

Division: BPPD

Service Requested: ☐ Fiche ☒ Paper ☐ Review Only ☐ CO

(Note: Only MRIDs > 44027700

are available on CD)

Type of Document: ☐ Accession ☒ MRID ☐ Tox Review
☐ PR Notice ☐ RED ☐ Fact Sheet
☐ OPP Publication ☐ Other

Reason for Request: ☐ Re-registration ☒ Registration
☐ Special Review ☐ Compliance Enforcement
☐ FOIA ☐ 6A(2)
☐ Other

Document(s) Requested:

43990001

Handwritten signature and the number 8

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Contractor Work

Performed by:

Tm

Time In:

3/27/03

8:45 AM

EPA QC Work

Performed by:

gj

Time Out:

3-27-03

11:05

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Dr. Bill Biehn
Technology Center of New Jersey
581 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

REC 1 1 1999

Letter
Sec 3
EUP
data leg

Dear Dr. Biehn:

Subject: *Aspergillus flavus* AF36 on cotton in Arizona
Experimental Use Permit Yearly Report
Proposed Section 3 Registration

Below are the data required (a) in the yearly report of the extended Experimental Use Permit (EUP) and (b) a description of data required for the Section 3 registration for *Aspergillus flavus* AF36 on cotton in Arizona. These requirements are summarized in bold and a brief discussion of the rationale behind each of the data requirements follows each requirement.

I. Extended EUP Yearly Report

A. Health effects

1. **DATA REQUIRED for Quality Assurance** - The yearly report for the EUP must include a summary of the analyses for each batch, showing levels of (a) aflatoxin and (b) human pathogen and other contaminant(s) in the batches and notations of the batches destroyed. During the EUP extension, details of the laboratory tests supporting these summarized data reports must be kept in your records and are subject to audit.

Quality Controls (product identity and aflatoxin production): In the yearly report for the EUP, provide summaries of records to demonstrate that:

(a) The fungus present on the wheat seeds is AF36. This identification can be done by vegetative compatibility.

(b) *A. flavus* AF36 has not acquired the ability to produce aflatoxins (i.e., test for aflatoxins). You must include in your records notation of *A. flavus* AF36 batches which were destroyed because of any significant level of aflatoxin produced by that batch. Details of these batch analyses must be maintained in your laboratory or production records and are subject to audit.

Quality Controls (human pathogens and other microbial contaminants): Quality control measures must be identified, reported to the Agency, and implemented to indicate what levels of contaminants are

SB:7511C:113099:69224EUP1:71693R:006456

CONCURRENCES

MBOL	7511C	7511C	7511C	7511C	7511C	7511C	383
RNAME	Lucas	Watson	SUNSHINE	ROUGER	Tommaso	It. ATN	

considered acceptable. This includes human pathogens, as well as other contaminating microbes. Batches of the pesticide containing contaminants above regulatory levels, must be destroyed.

B. Ecological Effects

For a detailed discussion of the ecological data requirements below, see the attached DERs by Dr. Doug Gurian-Sherman. If discussion about the protocols or any other further clarification about field monitoring is needed, feel free to consult with us.

1. **DATA REQUIRED - air monitoring of spores:** Data for each of two seasons must be included in the annual report of the EUP and submitted in support of the proposed Section 3 registration.

During the EUP, air monitoring of spores is required to determine whether total *A. flavus* spore production in treated cotton fields is significantly higher than in untreated fields. Data presented in Volume 1 of the study, completed 12/8/98, suggest that *A. flavus* inoculum production in treated fields is typically not higher than in untreated agricultural fields. However, the studies presented were not designed to determine whether this is true, and therefore air sampling studies of *A. flavus* conidia in treated and untreated fields are required. Reports must include data from July through October of each season. If the genetic marker test is available (see DATA REQUIREMENT 2 for human health effects below) provide data to demonstrate the relative proportions of AF36 to total *A. flavus*. These data are required because pulmonary exposure is an important route for avian aspergillosis infection.

2. **DATA REQUIRED - Propagules in cotton field soil:** Collect data to determine the amount of *A. flavus* propagules in cotton field soil and on the crop at maturity.

Data presented to demonstrate the lack of change in the amount of propagules in cotton field soil one year following treatment, and on the crop at maturity, were sufficient to support the proposed expanded EUP. However, these reports demonstrated a high level of variability. Because this risk assessment relies substantially on exposure data and AF36 is a possible pathogen, the Agency requires analyses of these soil samples, at least for an additional year, to support your application for full Section 3 registration.

II. SECTION 3 REGISTRATION DATA REQUIREMENTS

The following data are required for the Section 3 registration. Some of these requirements are described in detail above under the EUP since they are routine analyses required for record-keeping.

A. Health Effects

1. **DATA REQUIRED -** During production you must submit summaries of the Quality Assurance reports of all production batches for (a) aflatoxin and (b) human pathogen contaminants and other contaminants and metabolites of toxicological concern. Your report must include notations of the batches of *A. flavus* AF 36 destroyed on the basis of aflatoxin or any other contamination above regulatory levels.

Quality Control: To ensure that production batches are consistent, you must continue to monitor them as required above for the EUP extension. Provided that the manufacturing process remains unchanged, and the production batches meet Agency requirements, frequency of the testing may decrease. The requirement will always remain to destroy batches (lots) containing contaminants of

toxicological concern. Such contaminants include either aflatoxin producing *A. flavus*, or aflatoxin itself, or other human pathogens or microbial contaminants or any other potentially toxic metabolites. Only summaries of these tests must be submitted to the Agency. Details of these data must be available for laboratory audits or other enforcement actions as required under the regulations. If the manufacturing method changes from that used for the EUP, you must submit appropriate product identity, product chemistry, and quality control/assurance data to support the new manufacturing method..

2. DATA REQUIRED - A genetic marker test or other more definitive Quality Assurance procedure is required to distinguish *A. flavus* AF 36 from other *A. flavus* species.

An attempt must be made to develop another tool/mechanism, rather than plus/minus vegetative compatibility to differentiate *Aspergillus flavus* AF36 from other *A. flavus* species. Such a test may be a genetic marker or another mechanism sensitive enough to differentiate and enumerate the population of AF 36 in cotton field samples. In other words, the detection limit should provide adequate assurance that the population of AF 36, versus other *A. flavus* strains can routinely and accurately be determined. For additional information regarding this requirement see Agency memorandum dated May 14, 1999 from Michael T. Watson to Shanaz Bacchus.

3. DATA REQUIRED - Acute pulmonary toxicity/pathogenicity study in appropriate mammalian model.

Acute pulmonary toxicity/pathogenicity in mammals: Because no data have been submitted for the EUP to demonstrate the acute pulmonary toxicity/pathogenicity of *A. flavus* AF36 to mammals, guideline studies conducted in an appropriate mammalian model are required for a Section 3 registration.

B. Ecological Effects

In addition to the air and soil monitoring of spores discussed above, the Agency requires the following ecological effects data to support the Section 3 registration. It is recommended that you use two different species of birds for the avian acute oral and acute pulmonary studies (1 and 2 below). These two data requirements can be discussed with Agency scientists at a teleconference, if necessary.

1. DATA REQUIRED - Based on the observations below, an acute avian oral toxicity/pathogenicity study is required in order to determine the ecological effects of AF36 on avian species to satisfy guideline requirements. These data will be required for the Section 3 registration.

Acute oral toxicity/pathogenicity to birds. Bird census data (MRID 444642-02), submitted in support of the permit, suggest that native bird species are present in cotton fields in Arizona during and after pesticide application. Both studies which present census data (MRID 444642-02 and 444526-15) conclude that red wing blackbirds are the predominant species in cotton fields. However, MRID 444642-02, Table V, demonstrates that many other species are present in cotton fields at frequencies (~15 - 100%) comparable to adjacent native habitat. In addition, MRID 444642-02 reported that a significant proportion of birds were foraging in the fields. MRID 444526-15 demonstrated much lower percentage of foraging, but suggested that this was due to experimental difficulties and that actual percentages were likely to be much higher. MRID 444779-01 has also been reviewed, but the extensive census data of the other two studies are more relevant to risk assessment of the current biopesticide. Therefore, even if the amount of treated wheat applied (10 lb/A) would not be enough to attract birds to cotton fields, birds are present in any case and are likely to find some of the seed. Consequently, an acute avian oral toxicity/pathogenicity study is required.

2. DATA REQUIRED - Avian acute pulmonary toxicity/pathogenicity study in the northern bobwhite quail.

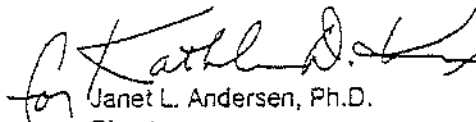
Avian Acute Pulmonary Pathogenicity: *A. flavus* is a known pathogen of birds. Because birds are expected to be present in cotton fields after sporulation of AF36, there is a potential for pulmonary exposure to avian species. An avian acute pulmonary toxicity/pathogenicity study in the northern bobwhite quail is required to ascertain the effects of *A. flavus* AF36 on birds.

3. DATA REQUIRED - Non-target study to demonstrate effects on honey bee.

Non-target bee data: The published literature indicates that several bee species are pollinators of cotton, and may be present in cotton fields at flowering, when AF36 treated wheat would be present. *A. flavus* is known to cause stone brood of honey bees, and therefore hive exposure studies are required. Since preliminary data, discussed above, suggests that exposure is probably not higher for bees in treated than untreated fields, these studies may be performed during the EUP and submitted in support of the Section 3 registration.

The data discussed above must be submitted in the yearly report of the EUP and/or in support of the Section 3 registration as indicated in this letter. A summary of the time frame for the submission of the data is provided in the Attachment (1 page). The proposed time frame indicates that potential Section 3 registration depends on the acceptability of the EUP data. If you have any further questions, do not hesitate to call Shanaz Bacchus at 703-308-8097.

Sincerely,



Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division.

cc: Larry Attila
J. Maguire

Summary of data requirements for the EUP yearly report and the proposed Section 3 registration for *A. flavus* AF36 on cotton in Arizona

Data requirements for the EUP yearly report		
Guideline	Data required	Required by
151-20 through 151-25	Summary analyses of each batch, product identity, levels of aflatoxin and other contaminant analyses	Jan 2000 Nov/Dec 2000
Case by case: Similar to 40 CFR 158.640: Gdln. 93-16	Product performance, Efficacy testing of fungicide, product for control of organisms producing mycotoxins - air and soil monitoring of <i>A. flavus</i> spores	Jan 2000 Nov/Dec 2000
Data requirements for Section 3 registration		
Guideline	Data required	Required by
	Data from EUP yearly report above	Nov/Dec 2000
151-20 through 151-25	Genetic marker test for identification of <i>A. flavus</i> AF36; Summary analyses of each batch, product identity, levels of aflatoxin and other contaminant analyses	March 2000 Nov/Dec 2000
154-16	Avian acute oral toxicity/pathogenicity	Nov/Dec 2000
154-17	Avian acute pulmonary toxicity/pathogenicity	Nov/Dec 2000
154-24	Honey bee testing	Nov/Dec 2000

Personal privacy information



Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

05/29/03 09:48 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Shanaz Bacchus [REDACTED] Peter Cotty
<pjcotty@srrc.ars.usda.gov>
Subject: RE: ATCC #/Trade mark?

Shanaz

The ATCC# is 96045.

There is no trademark.

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, May 29, 2003 8:44 AM
To: Mike Braverman
Cc: Shanaz Bacchus; Peter Cotty
Subject: ATCC #/Trade mark?

1. More nit picking....what is the ATCC # for AF36?
2. Is AF36 a trade mark? If so, it's not on the label as such...or anywhere else. Do advise.

Thanks.

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026



Joel Gagliardi
03/20/03 03:39 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
CC:
Subject: Re: Trichodex Daphnia Study Completed DER

Shan,
There are no confidentiality claims.
Joel



Trichodex daphnia sec review.w

Shanaz Bacchus



Shanaz Bacchus
03/20/2003 03:35 PM

To: Joel Gagliardi/DC/USEPA/US@EPA
CC:
Subject: Re: Trichodex Daphnia Study Completed DER

Thanks, Joel. I'll be in the office on Tuesday and will be free either before 10 a.m. or after 1 p.m. If it doesn't have CBI, you can send me the electronic file right here on email and I'll access it from home.

see u then,
shawn
Joel Gagliardi



Joel Gagliardi
03/20/03 11:26 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
CC:
Subject: Trichodex Daphnia Study Completed DER

Shan,
This study was peer-reviewed and Zig and I signed off on it today.
Stop by and I will give you the DER and return the original study.
The DER is rated supplemental (generally scientifically sound but not performed according to OPPTS guidelines).
Flags are: Aerial application, or direct application to water., are not recommended. The LC50 is near the expected environmental concentration.
Joel

Federal Register: February 14, 2003 (Volume 68, Number 31)]
[Notices]
[Page 7554-7558]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr14fe03-90]

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0020; FRL-7289-9]

Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to
Establish an Exemption from a Tolerance for a Certain Pesticide
Microbial Agent in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide
petition proposing the establishment of regulations for residues of a
certain pesticide microbial agent in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2003-0020, must be
received on or before March 17, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or
through hand delivery/courier. Follow the detailed instructions as
provided in Unit I. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

- [bull] Crop production (NAICS code 111)
- [bull] Animal production (NAICS code 112)
- [bull] Food manufacturing (NAICS code 311)
- [bull] Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

t. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0020. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official

docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly

[[Page 7555]]

available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper,

will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. EPA Dockets. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments.

Once in the system, select "search," and then key in docket ID number OPP-2003-0020. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. E-mail. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP-2003-0020. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. By mail. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2003-0020.

3. By hand delivery or courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall 2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2003-0020. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes

any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.

[[Page 7556]]

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however,

EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and record keeping requirements.

Dated: February 6, 2003.
Phil Hutton,
Acting Director, Biopesticides and Pollution Prevention Division,
Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 and The Arizona Cotton Research and Protection Council

PP 8E5001

EPA has received a pesticide petition (PP 8E5001) from Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center, 681 U.S. Highway 1 South, North Brunswick, NJ 08902-3390 on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue Phoenix, Arizona 85040-2933 proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.1206 by establishing an amendment/

expansion of an existing tolerance exemption for the microbial pesticide *Aspergillus flavus* AF36 in or on the food and feed commodity cotton and its by products.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, the aforesaid Interregional Research Project Number 4 (IR-4), has submitted the following summary of information, data, and arguments in support of the pesticide petition on behalf of the Arizona Cotton Research and Protection Council, however EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product name and Proposed Use Practices

Aspergillus flavus AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, is proposed for application to cotton to reduce the incidence of aflatoxin producing strains of *Aspergillus flavus* and thereby reduce aflatoxin contamination of cottonseed. When applied just prior to flowering, *Aspergillus flavus* AF36 which does not produce aflatoxin, competitively excludes aflatoxin producing *Aspergillus flavus* strains without increasing *Aspergillus flavus* in the environment in the long term. Sterile wheat seed colonized with *Aspergillus flavus* AF36 is applied at 10 lb of end-use product (total amount of active ingredient less than 0.01 lb/acre) per acre. The pesticide is currently being used in certain counties in the States of Arizona and Texas under an Experimental Use Permit (EPA Reg. No. 69224-EUP-1). The current submission proposes to establish a permanent exemption from tolerance for residues of *Aspergillus flavus* AF36 on cotton and its byproducts.

B. Product Identity/Chemistry

1. Identity of the pesticide and corresponding residues. The pesticide and corresponding residues are identified as *Aspergillus flavus* AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*.

2. Magnitude of residue at the time of harvest and method used to determine the residue. *Aspergillus flavus* AF36 is a naturally occurring fungus isolated from cottonseed produced in the Yuma Valley of Arizona. *Aspergillus flavus* AF36 has been shown to be naturally and consistently associated with commercial cotton grown in Arizona. Other than

immediately after application, the overall quantity of *Aspergillus flavus* at time of harvest on cottonseed grown in fields where *Aspergillus flavus* AF36 has been applied and has been shown to be similar to levels on cottonseed grown in fields where no application was made. *Aspergillus flavus* is a widespread fungus. It is particularly well adapted to the hot desert regions of Arizona where it is widespread in the environment. The communities of *Aspergillus flavus* in the desert and in agricultural fields are naturally composed of both aflatoxin producing (toxigenic) and aflatoxin non-producing (atoxigenic) strains. Both atoxigenic and toxigenic strains have been found on essentially all plant material and soils in the desert valleys of Arizona. The goal of applications is to increase the percent of the *Aspergillus flavus* community composed of the atoxigenic strain AF36 and to decrease the percent of *Aspergillus flavus* that produces aflatoxins on the crop and in the fields.

3. A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed. An exemption from the requirement of a tolerance for residues of the microbial pesticide *Aspergillus flavus* AF36 in/on cotton is being proposed for cotton treated in Arizona and Texas. *Aspergillus flavus* isolate AF36, when applied to the soil just prior to bloom has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Aflatoxin levels in cottonseed products are regulated by the Food and Drug Administration (FDA). FDA does not allow cottonseed products containing aflatoxin at 20 parts per billion (ppb), or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin above 300 ppb, to be used for feeding beef cattle. All lots of the active ingredient (*Aspergillus flavus* isolate AF36) and the formulated products are monitored for aflatoxin production as part of a rigorous quality control program. Starter cultures of *Aspergillus flavus* isolate AF36 used in the production of the end-use product are always screened for strain identity by vegetative

[[Page 7557]]

compatibility, and for aflatoxin production using thin layer chromatography and appropriate standards. Quality control standards are zero tolerance in the starter cultures and in the formulated product for aflatoxin production, and for *Aspergillus flavus* not identified as *Aspergillus flavus* isolate AF36. *Aspergillus flavus* AF36 has never been found to produce aflatoxin.

C. Mammalian Toxicological Profile

An acute oral toxicity test was performed whereby a single oral dose of 5,000 milligrams/kilogram body weight (mg/kg/bwt) per animal of *Aspergillus flavus* AF36 colonized wheat seed was administered by gavage to five male and five female Sprague Dawley rats. The oral LD50 of *Aspergillus flavus* AF36 was determined to be greater than 5,000 mg/kg rat body weight. No clinical signs were observed during the 14-day study and no abnormalities or adverse effects were observed in any of the rats upon necropsy.

An initial pulmonary rat study resulted in lethality in a significant number of animals treated with either the live *Aspergillus flavus* AF36 in Tween 80 or heat killed *Aspergillus flavus* AF36 in Tween 80. Onset of symptoms was rapid after dosing with all deaths occurring by day 4 of the study. All rats surviving to day 4 of the study recovered and all rats sacrificed (as scheduled) on day 8 or day 15 of the study had totally eliminated viable *Aspergillus flavus* AF36 from the lungs, caecal contents, and feces. There was no evidence of infectivity. The aetiology of deaths was unclear. It appeared that *Aspergillus flavus* AF36 prepared as a test substance with Tween 80 caused a severe acute inflammatory response. Retrospective literature review and consultation with a toxicologist supported the theory that the responses were a result of a synergism with Tween 80 and/or of Tween 80 breakdown products formed during preparation of the spore suspension test substance.

A second rat pulmonary study was therefore undertaken. In the second study the conidia were both washed from the wheat and suspended in sterile physiological saline instead of Tween 80. Animals (2 male and 2 female for each treatment level) were dosed at 0, 10⁵, 10⁶, 10⁷, and 10⁸ colony forming units per rat. There were no clinical signs in any of the treatment groups considered to be associated with the test substance. Rats were sacrificed at day 8 without treatment associated mortality. No abnormalities were observed in any of the animals at the macroscopic examination at termination.

Based on these two mammalian studies, the petitioner concludes that *Aspergillus flavus* AF36 does not present either a toxicological or an infectious risk to mammals. Data waivers were requested for the following toxicology studies: Acute dermal toxicology/pathology, primary dermal irritation, primary eye irritation, and acute intraperitoneal toxicology/pathology effects of the microbial pesticide. The following rationales were used as a basis for the data waiver requests:

[sbull] Researchers and other workers have worked with *Aspergillus flavus* AF36 at the Southern Regional Research Center for over 10 years

and in commercial fields (1996 to 1998) and in hand-picked field plots (1989 to 1994) without report of any adverse health effects.

[sbull] *Aspergillus flavus* AF36 is widely distributed in the environment and its occurrence is natural.

[sbull] The label will require applicators and other handlers to wear Personal Protective Equipment (PPE) such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks, and goggles, to mitigate against dermal and primary eye irritation exposure.

The pesticide is to be applied aerially by mixers/handlers and applicators who are licensed and trained to handle restricted materials. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre. Applications of AF36 do not significantly impact the total amount of *Aspergillus flavus* in the soil or crop, but only change the proportion of the AF36 strain in relation to the overall soil population. Since the product is applied to cotton fields as a granular formulation on colonized wheat seeds, exposure from drift is minimal.

In addition, the following rationales were advanced in support of the data waiver requests for acute dermal toxicity and primary dermal irritation. These studies were waived during the experimental use program, based upon the lack of toxicity in animals dosed orally. While other *Aspergillus flavus* strains have been reported to be dermal sensitizers, this testing is not warranted, since the aerial method of application and the PPE required on the label will mitigate dermal exposure to workers and pesticide handlers. The acute intraperitoneal study was waived based upon the lack of toxicity in animals dosed orally and by pulmonary/intratracheal instillation.

Genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity testing were not performed, since no adverse effects were observed in the acute toxicology study Tier I studies. Tier II (885.3550), subchronic toxicology study (EPA OPPTS 885.3600) and chronic feeding studies (guideline 152-50) are only required if triggered by adverse effects observed in Tier I studies.

D. Aggregate Exposure

1. Dietary exposure--i. Food. *Aspergillus flavus* AF36 is a naturally occurring organism, which does not produce aflatoxin and is thus safer than the aflatoxin-producing *Aspergillus flavus* isolates. Proposed uses and application rates will not result in increases in the total population of *Aspergillus flavus* on the mature crop beyond

naturally occurring background levels. FDA does not allow cottonseed products containing aflatoxin at 20 ppb or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin levels above 300 ppb, to be used for feeding beef cattle.

Aspergillus flavus AF36, when applied to the soil just prior to bloom, has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Furthermore, the proposed use and application rate will not increase exposure of humans to *Aspergillus flavus* by dietary means, since cotton itself is not a food product for human consumption. There is minimal dietary exposure to *Aspergillus flavus* from cottonseed. There is no mechanism for *Aspergillus flavus* to be transferred from the seed to animal products and there is no evidence that the fungus readily contaminates meat or milk. Seed is typically extracted for oil with hexane and that process kills the fungus. Furthermore, applications of *Aspergillus flavus* AF36 do not increase the indigenous populations of *Aspergillus flavus* associated with the harvested crop. The applications merely alter the composition of the fungal community associated with the mature crop so that aflatoxin producing strains are far less frequent. The result is a much lower incidence of aflatoxins in the crop and in the environment associated with the developing and mature crop.

ii. Drinking water. *Aspergillus flavus* AF36 is a naturally occurring organism that is already widespread in the environment and is not considered to be a risk to drinking water. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure of *Aspergillus flavus* through the drinking

[[Page 7558]]

water. Applications of *Aspergillus flavus* AF36 do not increase the long-term populations of *Aspergillus flavus* in the environment, and thus are not expected to influence the relationship of *Aspergillus flavus* to water sources. Applications merely change the composition of the *Aspergillus flavus* community so that aflatoxin producing strains are less common in the environment.

2. Non-dietary exposure. The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant and is not expected to present any risk of adverse health effects.

E. Cumulative Exposure

There are no other registered products containing *Aspergillus flavus* AF36 or any other isolates (strains) of the microbial active ingredient. Data submitted show that the fungal metabolite of concern, which is aflatoxin, is not produced by *Aspergillus flavus* AF36 in the crop or in artificial media in the lab. When applied prior to flowering, *Aspergillus flavus* AF36 has been shown to exclude aflatoxin producing fungi competitively from the developing crop and to reduce aflatoxin contamination of cottonseed. Data show that the proposed use will not result in appreciable increases in the long-term population of *Aspergillus flavus* on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

F. Safety Determination

1. U.S. population. *Aspergillus flavus* AF36 is a naturally occurring organism. This isolate has low toxicity as demonstrated by the acute oral toxicity study in rats. *Aspergillus flavus* is ubiquitous throughout the hot desert valleys in Arizona. Studies have shown that treatment of cotton fields just prior to flowering with sterile wheat seed colonized by *Aspergillus flavus* AF36 at 10 lb per acre does not increase the long-term populations of *Aspergillus flavus* either on the crop at maturity or in the soil 1 year after application. Based on this information, Interregional Research Project Number-4 is of the opinion that the aggregate exposure to *Aspergillus flavus* over a lifetime should not change with application of *Aspergillus flavus* AF36, and exposure to both aflatoxin producing *Aspergillus flavus* strains and aflatoxin should decrease. This should be beneficial to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to *Aspergillus flavus* AF36.

2. Infants and children. Based on the lack of toxicity and natural occurrence, there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to *Aspergillus flavus* AF36. Exempting *Aspergillus flavus* AF36 from the requirement of a tolerance should pose no significant risk to humans or the environment.

G. Effects on the Immune and Endocrine Systems

Aspergillus flavus AF36 is a naturally occurring organism, which

does not produce aflatoxin, and is thus safer than the *Aspergillus flavus* isolates that produce aflatoxin. To date there is no evidence to suggest that *Aspergillus flavus* AF36 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Efficacy

Existence of aflatoxins in the environment is a public health hazard. Data were submitted to demonstrate that proper use of *Aspergillus flavus* AF36 results in reductions in the average aflatoxin producing potential of fungi resident in treated areas and in reductions in the quantity of aflatoxins in crops. In field tests prior to 1996, the aflatoxin content of cottonseed was shown to be inversely related to the proportion of the *Aspergillus flavus* community on the crop composed of *Aspergillus flavus* AF36. Detailed analyses of the aflatoxin content of commercial fields from 1996 through 1998 confirmed that reduced aflatoxin levels were associated with displacement of aflatoxin producers by *Aspergillus flavus* AF36 from treated crops and that treatments were associated with up to 90% reductions in crop aflatoxin content.

Efficacy of applications of *Aspergillus flavus* AF36 in displacing aflatoxin producers was demonstrated for fungal communities both on cottonseed from treated crops at harvest and in soils of treated fields 1 year after treatment. This included cotton crops treated in 1996 (112 acres treated), 1997 (463 acres treated), 1998 (499 acres), 1999 (10,488 acres), 2000 (16,725 acres), and 2001 (19,975 acres treated). The proportion of *Aspergillus flavus* communities composed of *Aspergillus flavus* AF36 indicates the extent to which aflatoxin producers were displaced. In 1996 average incidence of AF36 on treated crops was 88.5% and in the soil, 1 year after treatment, incidence of AF36 was 85.2%. Incidences of AF36 on treated crops were 78% and 67% in 1997 and 1998, respectively, and in soil 1 year after treatment, AF36 incidences were 72% and 77%, respectively. Successful displacement was also observed as the acreage treated rapidly expanded from 1999 to 2001 with average incidences of AF36 on treated crops ranging from 57% in 1999 to 66% in 2001.

Aflatoxin-producing S strain isolates of *Aspergillus flavus* are prominent in soils of cotton producing areas of Arizona and south Texas. They produce more aflatoxins than other *Aspergillus flavus* isolates such as the non-aflatoxin-producing L strain *Aspergillus flavus* AF36. Applications of AF36 during the experimental program were effective at displacing the high aflatoxin producing S strain of *Aspergillus flavus*. During the course of the experimental use program,

Aspergillus flavus AF36 also caused long-term reductions in the aflatoxin producing potential of fungal communities in agricultural fields. Aspergillus flavus AF36 retained atoxigenicity (failure to produce aflatoxins) upon repeated reisolation from treated fields 1, 2, or 3 years after treatment. Thus, there was a long-term reduction in the potential of fungal communities to produce aflatoxins in treated areas. The average aflatoxin producing potential of Aspergillus flavus communities resident in soils of treated fields was reduced on average 73% 1 year after treatment over the 3 year period (1996 to 1999). S strain isolates, which produced very high levels of aflatoxins, with field averages ranging from 7,100 ppb, aflatoxin to 22,700 ppb, aflatoxin, were effectively displaced. Their incidence was reduced from initially composing 46% of Aspergillus flavus soil communities to composing on average of 11%.

I. Existing Tolerances

The registrant is not aware of any existing tolerances or tolerance exemptions for Aspergillus flavus AF36, other than the temporary tolerance exemption on cotton (40 CFR 180.1206) in conjunction with an EUP, which expires on December 30, 2004.

J. International Tolerances

There are no Codex maximum residue levels established for residues of Aspergillus flavus AF36. Aspergillus flavus AF36 containing products are presently not registered for pest control outside of the United States.

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Interregional Research Project No. 4
Center for Minor Crop Pest Management

FAX

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Number of pages including cover page? 2

Letter of authorization

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July 30, 2002

RE: *Aspergillus flavus* AF-36
Section 3 registration

Dear Dr Andersen:

This letter authorizes the Environmental Protection Agency to refer to the USDA/ARS Southern Regional Research Center data on *Aspergillus flavus* when considering the application for registration for *Aspergillus flavus* AF-36 submitted for the Arizona Cotton Research and Protection Council by the IR-4 Project. This includes all data previously submitted for both the Experimental Use Permit and Section 3 registration.

Sincerely,

Peter J. Cotty, Ph.D.
Research Plant Pathologist

Study Title

Aspergillus Flavus isolate AF36 - Analysis of Samples,
Certification of Ingredient Limits, Analytical Methods for
Certified Limits
Amendment No. 2 to MRID No. 43763402

Data Requirement

Subdivision M, Guideline 151A-13 and 151A-15

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Project I.D. Number

IR-4 PR No. 52B

